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# Virotech Patents, Viropiracy, and Viral Sovereignty

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# VIROTECH PATENTS, VIROPIRACY, AND VIRAL SOVEREIGNTY

Peter K. Yu\*

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\*. Copyright © 2014 Peter K. Yu. Kern Family Chair in Intellectual Property Law and Director, Intellectual Property Law Center, Drake University Law School; Visiting Professor of Law, Faculty of Law, Haifa University. Earlier versions of this Article were presented at the Second International Intellectual Property Scholars Roundtable at the University of San Diego School of Law, the 2013 Works-in-Progress Intellectual Property Colloquium at Seton Hall University School of Law, the *UMKC Law Review* Symposium on “Intellectual Property and Technology Transfer” at UMKC School of Law, the *John Marshall Review of Intellectual Property Law* Symposium on “Biotechnology and Health-Related Issues in IP Law” at John Marshall Law School, the 2003 Annual Meeting of Law and Society Association in Pittsburgh, and in the Faculty Speaker Series at Georgia State University College of Law. The Author is grateful to Yaniv Heled, Chris Holman, Michael Landau, and Lisa Ramsey for their hospitality and Margo Bagley, Yaniv Heled, and the other participants of these events for their valuable comments and suggestions. He would also like to thank Linzey Erickson, La’Cee Groetken, and Kyle Mendenhall for excellent research and editorial assistance.

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## INTRODUCTION

Access to medicines goes hand in hand with the protection of intellectual property rights. At a time when the United States is undertaking large-scale reforms in both the intellectual property and healthcare arenas, it is worth thinking more deeply and broadly about the connections between the two. In March 2010, Congress enacted the Patient Protection and Affordable Care Act<sup>1</sup> and the Health Care and Education Reconciliation Act of 2010.<sup>2</sup> The passage of these highly controversial statutes led to a constitutional challenge to the first statute before the United States Supreme Court. In the 5–4 decision of *National Federation of Independent Business v. Sebelius*, Chief Justice John Roberts upheld the statute's individual mandate while striking down its Medicaid expansion provisions.<sup>3</sup>

In the intellectual property arena, Congress enacted the Leahy-Smith America Invents Act<sup>4</sup> in September 2011, providing a complete overhaul of the U.S. patent system. The next year, high-stakes patent trials resulted in three eye-popping verdicts, each exceeding \$1 billion.<sup>5</sup> By the end of the 2012 Term, the United States Supreme Court has reviewed an unusually large number of patent cases.<sup>6</sup> As Timothy Holbrook reminded us:

Starting in around 2000, the Supreme Court became active, if not even hyperactive, in patent law. . . . Additionally, the Supreme Court's intervention is no longer on the periphery of patent law. The cases they have decided go right to the substance of patent law: the doctrine of equivalents and prosecution history estoppel, subject matter eligibility, induced infringement, the statutory experimental use defense, to name but a few.<sup>7</sup>

Of great interest in the 2012 Term was *Association for Molecular Pathology v. Myriad Genetics, Inc.*<sup>8</sup> Lying at the intersection of intellectual

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1. Pub. L. No. 111-148, 124 Stat. 119 (2010).

2. Pub. L. No. 111-152, 124 Stat. 1029 (2010).

3. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2608 (2012).

4. Pub. L. No. 112-29, 125 Stat. 284 (2011).

5. See Amanda Bronstad, *IP Awards Dominate*, NAT'L L.J., Mar. 4, 2013, <http://www.law.com/jsp/nlj/PubArticleNLJ.jsp?id=1202590587509&slreturn=20131006195123> (reporting the verdicts from the lawsuit Carnegie Mellon University filed against Marvell Technology, the lawsuit Apple filed against Samsung Electronics, and the lawsuit Monsanto filed against DuPont).

6. For a discussion of the Court's growing interest, see generally Timothy R. Holbrook, *Explaining the Supreme Court's Interest in Patent Law*, 3 IP THEORY 62 (2013).

7. *Id.* at 63–64 (footnotes omitted).

8. 133 S. Ct. 2107 (2013).

property and public health, this case concerned the patentability of composition and method claims covering two isolated human genes associated with breast and ovarian cancers as well as their alterations and mutations. In a surprisingly short decision, Justice Clarence Thomas held that “a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that [synthetically created DNA segment known as complementary DNA] is patent eligible because it is not naturally occurring.”<sup>9</sup> He further noted that the case did not involve patent claims in “an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes,” “patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes,” and “the patentability of DNA in which the order of the naturally occurring nucleotides has been altered.”<sup>10</sup> Although it is too early to assess the full implications of this narrowly written decision, it is not hard to appreciate the decision’s potential impact on U.S. biotechnology and life science industries. *Myriad Genetics* will also raise important questions about the appropriate level of patent protection in relation to the development of biologics<sup>11</sup> and diagnostic kits.<sup>12</sup>

At the international level, there has been a decade-long, but still vibrant, debate about the major impediments the Agreement on Trade-Related Aspects of Intellectual Property Rights<sup>13</sup> (“TRIPS Agreement”) has generated to access to essential medicines in less developed countries—a term used collectively to cover both developed and least developed

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9. *Id.* at 2111.

10. *Id.* at 2119–20.

11. For discussions of intellectual property issues in relation to biologics, see generally Donna M. Gitter, *Innovators and Imitators: An Analysis of Proposed Legislation Implementing an Abbreviated Approval Pathway for Follow-on Biologics in the United States*, 35 FLA. ST. U. L. REV. 555 (2008); Christopher M. Holman, *Maintaining Incentives for Healthcare Innovation: A Response to the FTC’s Report on Follow-on Biologics*, 11 MINN. J.L. SCI. & TECH. 755 (2010); Gregory N. Mandel, *The Generic Biologics Debate: Industry’s Unintended Admission that Biotech Patents Fail Enablement*, 11 VA. J.L. & TECH. 8 (2006); Symposium, *Follow-on Biologics: Implementation Challenges and Opportunities*, 41 SETON HALL L. REV. 501 (2011).

12. See, e.g., EDSON BEAS RODRIGUES JR., THE GENERAL EXCEPTION CLAUSES OF THE TRIPS AGREEMENT: PROMOTING SUSTAINABLE DEVELOPMENT 168–69 (2012) (discussing the impact of gene patents on the development of diagnostic kits); Rochelle C. Dreyfuss & James P. Evans, *From Bilski Back to Benson: Preemption, Inventing Around, and the Case of Genetic Diagnostics*, 63 STAN. L. REV. 1349, 1361–70 (2011) (providing a case study of patent-related issues arising in genetic diagnostics).

13. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 108 Stat. 4809, 869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

countries as identified within the World Trade Organization (“WTO”).<sup>14</sup> Since the TRIPS Agreement entered into force in January 1995, it not only has taken away the wide policy space less developed countries once enjoyed at the international level,<sup>15</sup> but it has also resulted in needless deaths and suffering to patients that have acquired either the human immunodeficiency virus (“HIV”) or the Acquired Immune Deficiency Syndrome (“AIDS”).<sup>16</sup> The pandemic caused by HIV/AIDS, malaria, and tuberculosis has also greatly reduced the productivity of many countries in sub-Saharan Africa.<sup>17</sup>

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14. See Peter K. Yu, *The International Enclosure Movement*, 82 IND. L.J. 827, 858–62 (2007) (discussing these deleterious impacts). For book-length discussions of access-to-medicines problems in relation to the TRIPS Agreement, see generally SUDIP CHAUDHURI, *THE WTO AND INDIA’S PHARMACEUTICALS INDUSTRY: PATENT PROTECTION, TRIPS, AND DEVELOPING COUNTRIES* (2005); HOLGER HESTERMEYER, *HUMAN RIGHTS AND THE WTO: THE CASE OF PATENTS AND ACCESS TO MEDICINES* (2008); CYNTHIA M. HO, *ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS* (2011); INTELLECTUAL PROPERTY, PHARMACEUTICALS, AND PUBLIC HEALTH: ACCESS TO DRUGS IN DEVELOPING COUNTRIES (Kenneth C. Shadlen et al. eds., 2012); VALBONA MUZAKA, *THE POLITICS OF INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO MEDICINES* (2011); NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES (Pedro Roffe et al. eds., 2006) [hereinafter NEGOTIATING HEALTH].

15. See generally Yu, *The International Enclosure Movement*, *supra* note 14, at 855–72 (discussing the growing enclosure of the policy space of less developed countries at the international level).

16. For discussions of access-to-medicines problems in relation to HIV/AIDS, see generally THE GLOBAL GOVERNANCE OF HIV/AIDS: INTELLECTUAL PROPERTY AND ACCESS TO ESSENTIAL MEDICINES (Obijiofor Aginam, John Harrington & Peter K. Yu eds., 2013) [hereinafter GLOBAL GOVERNANCE OF HIV/AIDS]; THE POLITICAL ECONOMY OF HIV/AIDS IN DEVELOPING COUNTRIES: TRIPS, PUBLIC HEALTH SYSTEMS AND FREE ACCESS (Benjamin Coriat ed., 2008) [hereinafter POLITICAL ECONOMY OF HIV/AIDS].

17. See FRANKLYN LISK, *GLOBAL INSTITUTIONS AND THE HIV/AIDS EPIDEMIC: RESPONDING TO AN INTERNATIONAL CRISIS* 82–92 (2009) (discussing the impact of HIV/AIDS on human resource capacity); Wolfgang Hein et al., *Introduction: Globalization, HIV/AIDS and the Rise of Global Health Governance*, in GLOBAL HEALTH GOVERNANCE AND THE FIGHT AGAINST HIV/AIDS 1, 7 (Wolfgang Hein et al., eds., 2007) [hereinafter FIGHT AGAINST HIV/AIDS] (“HIV/AIDS and infectious diseases strike hardest at the productive parts of the population, at the pool of experienced individuals that would qualify for leading positions in society, leading to economic decline.”); Colin McInnes, *National Security and Global Health Governance*, in GLOBAL HEALTH GOVERNANCE: CRISIS, INSTITUTIONS AND POLITICAL ECONOMY 42, 48 (Adrian Kay & Owain David Williams eds., 2009) [hereinafter GLOBAL HEALTH GOVERNANCE] (noting the “disproportionate impact [of HIV/AIDS] upon workers in what should be the most productive period of their lives”); Geoff Tansey, *Introduction: Legal Fictions and Public Health*, in NEGOTIATING HEALTH, *supra* note 14, at 1, 2 (noting that, in rural Africa, “HIV/AIDS is devastating farming families and undermining their ability to farm”); Srividhya Ragavan, *The Jekyll and Hyde Story of International Trade: The Supreme Court in PhRMA v. Walsh and the TRIPS Agreement*, 38 U. RICH. L. REV. 777, 821 (2004) [hereinafter Ragavan, *Jekyll and Hyde*] (“An epidemic increase of AIDS reduced life expectancy and affected labor and economic output, as the younger casualties increase. Consequently, national productivity declined in several developing nations since the loss of labor from the loss of each life affected a proportionate value of output.” (footnotes omitted));

In December 2013, WTO member states met in the Ninth Ministerial Conference in Bali, with the hope of reviving the Doha Development Round of Trade Negotiations (“Doha Round”).<sup>18</sup> This ministerial conference was held a few months after WTO members agreed at the Council for Trade-Related Aspects of Intellectual Property Rights (“TRIPS Council”) to extend the transition period for least developed countries.<sup>19</sup> Article 66 of the TRIPS Agreement initially set the period at ten years.<sup>20</sup> In November 2005, shortly before the Sixth Ministerial Conference in Hong Kong, WTO members agreed to extend the period for seven-and-a-half years until July 1, 2013, as long as the extension-seeking country has not yet met the TRIPS requirements or has not already offered protection in excess of those requirements.<sup>21</sup> Building on Haiti’s formal request for another extension on behalf of the Least Developed Countries Group,<sup>22</sup> the June 2013 TRIPS Council decision further extended the transition period for eight years until July 1, 2021 without the earlier “non-rollback” commitment.<sup>23</sup>

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Yu, *The International Enclosure Movement*, *supra* note 14, at 855 (“At the macro level, health problems could also lower the productivity of a country—to the point that it will fall behind its trading partners in terms of economic development, technological innovation, industrial progress, and national competitiveness.”).

18. Press Release, World Trade Org. [WTO], Bali Ministerial to Be Held 3–6 December 2013 (Dec. 11, 2012), [http://www.wto.org/english/news\\_e/news12\\_e/gc\\_11dec12\\_e.htm](http://www.wto.org/english/news_e/news12_e/gc_11dec12_e.htm).

19. Press Release, WTO, The Least Developed Get Eight Years More Leeway on Protecting Intellectual Property (June 11, 2013), [http://www.wto.org/english/news\\_e/news13\\_e/trip\\_11jun13\\_e.htm](http://www.wto.org/english/news_e/news13_e/trip_11jun13_e.htm).

20. TRIPS Agreement art. 66.

21. Press Release, WTO, Poorest Countries Given More Time to Apply Intellectual Property Rules (Nov. 29, 2005), [http://www.wto.org/english/news\\_e/pres05\\_e/pr424\\_e.htm](http://www.wto.org/english/news_e/pres05_e/pr424_e.htm).

22. Communication from Haiti on Behalf of the LDC Group, *Request for an Extension of the Transitional Period Under Article 66.1 of the TRIPS Agreement*, IP/C/W/583 (Nov. 5, 2012). Haiti initially proposed to extend the transition period “for as long as the WTO Member remains a least developed country.” That proposal, though eventually failed, earned the support of the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Development Programme (UNDP), and more than 300 civil society organizations. See UNAIDS & UNDP, *TRIPS Transition Period Extensions for Least-developed Countries 6* (UNAIDS, Issue Brief, 2013), [http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2013/JC2474\\_TRIPS-transition-period-extensions\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2013/JC2474_TRIPS-transition-period-extensions_en.pdf) [hereinafter *UNAIDS/UNDP Issue Brief*] (calling on the WTO members to give “close and immediate attention” to the extension request from least developed countries); Catherine Saez, *WTO: LDCs to Press for Extension for TRIPS, Plain Packaging Back*, INTELL. PROP. WATCH (Feb. 26, 2013, 2:15 PM), <http://www.ip-watch.org/2013/02/26/wto-ldcs-to-press-for-extension-for-trips-plain-packaging-back> (reporting the support least developed countries received from UNAIDS, UNDP, and civil society organizations).

23. Council for Trade-Related Aspects of Intellectual Property [TRIPS Council], *Extension of the Transition Period Under Article 66.1 for Least Developed Country Members: Decision of the Council for TRIPS of 11 June 2013*, IP/C/64 (June 11, 2013). For discussions of

Notwithstanding this recent extension for least developed countries, there remains another deadline that is highly important to the global access to medicines debate. This deadline concerns the ratification of the protocol to amend the TRIPS Agreement, which WTO member states adopted also shortly before the Hong Kong Ministerial.<sup>24</sup> If ratified by two-thirds of the WTO membership, the new Article 31*bis* would allow countries with insufficient or no manufacturing capacity to import generic versions of patented pharmaceuticals. Although the initial deadline for ratification was December 1, 2007, that deadline has since been extended four times to December 31, 2015. As of this writing, slightly less than a third of the 159 WTO member states have ratified the proposed amendment.<sup>25</sup> If the amendment fails to attain the requisite ratifications by the new deadline, this deadline will have to be extended again.<sup>26</sup>

Sadly, with all the interrelated developments in the intellectual property and public health arenas both within and outside the United States, the domestic debate remains surprisingly disconnected from the international debate. Because of this disconnect, the laws and policies Congress and the administration adopt often do not synchronize with developments abroad. To help bridge this disconnect, this Article discusses the interrelationship between intellectual property and public health in the context of communicable diseases. This type of disease is intentionally picked to highlight how developments abroad could easily affect what happens at home, and vice versa.

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this extension, see generally Frederick M. Abbott, *Technical Note: The LDC TRIPS Transition Extension and the Question of Rollback* (ICTSD Programme on Innovation, Technology and Intellectual Property, Policy Brief No. 15, 2013), available at <http://ictsd.org/downloads/2013/05/the-ldc-trips-transition-extension-and-the-question-of-rollback.pdf>; Arno Hold & Bryan Christopher Mercurio, *After the Second Extension of the Transition Period for LDCs: How Can the WTO Gradually Integrate the Poorest Countries into TRIPS?* (NCCR Trade Regulation, World Trade Institute, University of Bern, Working Paper No. 2013/42, 2013), available at <http://ssrn.com/abstract=2302335>.

24. General Council, *Amendment of the TRIPS Agreement*, WT/L/641 (Dec. 8, 2005) [hereinafter *TRIPS Amendment*], available at [http://www.wto.org/english/tratop\\_e/trips\\_e/wtl641\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm); see also Yu, *The International Enclosure Movement*, *supra* note 14, at 872–86 (tracing the development of Article 31*bis* of the TRIPS Agreement).

25. *Members Accepting Amendment of the TRIPS Agreement*, WTO, [http://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm) (last updated Oct. 21, 2013) [hereinafter *Members Accepting Amendment*].

26. See General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, ¶ 11, WT/L/540 (Sept. 1, 2003), 43 I.L.M. 509 (2004) [hereinafter *August 30 Decision*] (stating that the waivers granted in this decision “shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member”).



Parts I to III of this Article recount three distinct “virostories”—stories about viruses responsible for AIDS, the Severe Acute Respiratory Syndrome (“SARS”),<sup>27</sup> and the avian influenza.<sup>28</sup> Part I discusses the ongoing developments within the WTO concerning efforts to address the access-to-medicines problems in relation to HIV/AIDS and other pandemics. Part II documents the unusual race among research and health institutions in Canada, Hong Kong, and the United States to patent technologies involving the isolated gene sequences of the SARS coronavirus. This Part also explores the use of patenting as a defensive measure and the development of patent pools as a solution to prevent the creation of a patent thicket. Part III examines the recent efforts by Indonesia, India, and other members of the Non-Aligned Movement to claim sovereignty over viruses found within their jurisdictions. This Part focuses on the H5N1 strain of the avian influenza virus in Indonesia.

To help illustrate the need to take a global, holistic, multidisciplinary socio-legal approach, which will be the focus of the second half of this Article, Parts I to III embrace the narrative technique. Such a technique enables the stories to be told in a way that would be meaningful to those participating in both the intellectual property and public health debates. The thick descriptions the article provides also highlight related issues on cross-border trade, global governance, human development, North-South relations, international sovereignty, human rights protection, and medical and biological ethics. With a wide range of characters, openings, plot twists, and endings, these virostories provide insight into the different facets of the international patent debate. By bringing together HIV/AIDS, SARS, and H5N1, this Article will further remind policymakers that the discussion on the TRIPS Agreement should not focus so much on the HIV/AIDS crisis in the less developed world to the point that they ignore other similar problems created by an out-of-balance intellectual property system.<sup>29</sup>

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27. For discussions of SARS, see generally THOMAS ABRAHAM, *TWENTY-FIRST CENTURY PLAGUE: THE STORY OF SARS* (2007); TIM BROOKES, *BEHIND THE MASK: HOW THE WORLD SURVIVED SARS, THE FIRST EPIDEMIC OF THE 21ST CENTURY* (2004); DAVID P. FIDLER, *SARS, GOVERNANCE AND THE GLOBALIZATION OF DISEASE* (2004); KARL TARO GREENFELD, *CHINA SYNDROME: THE TRUE STORY OF THE 21ST CENTURY'S FIRST GREAT EPIDEMIC* (2006); WORLD HEALTH ORG. [WHO], *SARS: HOW A GLOBAL EPIDEMIC WAS STOPPED* (2006) [hereinafter *HOW A GLOBAL EPIDEMIC WAS STOPPED*].

28. See generally AVIAN INFLUENZA: SCIENCE, POLICY AND POLITICS (Ian Scoones ed., 2010) [hereinafter *AVIAN INFLUENZA*] (discussing avian influenza).

29. As the U.K. Commission on Intellectual Property Rights reminded us:

It is particularly important not to allow the debate in [the intellectual property] area to be influenced unduly by the HIV/AIDS experience, dramatic though it is. Apart from HIV/AIDS, which is the biggest single cause of mortality in developing countries, TB and malaria claim almost as

Part IV draws seven important lessons from the three earlier narratives to advance a new, integrated approach to setting international intellectual property norms. This new approach takes account of both the existing problems concerning the TRIPS Agreement and the new problems precipitated by the negotiation of the Anti-Counterfeiting Trade Agreement (“ACTA”),<sup>30</sup> the Trans-Pacific Partnership (“TPP”) Agreement,<sup>31</sup> and other nonmultilateral trade and investment agreements.<sup>32</sup> Tying domestic laws and policies to the international debate, this Part focuses on three sets of issues that often come up in the international intellectual property norm-setting process: negotiation gains, the negotiation process, and negotiated outcomes.

By bringing together both the descriptive and the prescriptive, this Article seeks to drive home the message that the international intellectual property and public health debates could easily spill over into the domestic debates, and vice versa. Just as viruses do not recognize national boundaries<sup>33</sup>—as health professionals have repeatedly warned us—

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many lives. Together all three diseases claimed nearly six million lives [in 2001], and led to debilitating illness for millions more. In addition, there are a number of less common diseases which are collectively important. These include, for instance, measles, sleeping sickness, leishmaniasis and Chagas disease.

COMM’N ON INTELLECTUAL PROP. RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY: REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS 30 (2002) [hereinafter IPR COMMISSION REPORT] (footnote omitted).

30. Anti-Counterfeiting Trade Agreement, *opened for signature* May 1, 2011, 50 I.L.M. 243 (2011) [hereinafter ACTA].

31. See *Trans-Pacific Partnership*, OFFICE OF THE U.S. TRADE REP., <http://www.ustr.gov/tpa> (last visited Nov. 7, 2013) (providing up-to-date information about the TPP).

32. See, e.g., Central America–Dominican Republic–United States Free Trade Agreement, May 28, 2004 [hereinafter CAFTA-DR], available at <http://www.ustr.gov/trade-agreements/free-trade-agreements/cafta-dr-dominican-republic-central-america-fta/final-text>; United States–Australia Free Trade Agreement, U.S.–Austl., May 18, 2004 [hereinafter AUSFTA], available at <http://www.ustr.gov/trade-agreements/free-trade-agreements/australian-fta/final-text>; United States–Singapore Free Trade Agreement, U.S.–Sing., May 6, 2003 [hereinafter SUSFTA], available at [http://www.ustr.gov/sites/default/files/uploads/agreements/fta/singapore/asset\\_upload\\_file708\\_4036.pdf](http://www.ustr.gov/sites/default/files/uploads/agreements/fta/singapore/asset_upload_file708_4036.pdf). For discussions of bilateral, plurilateral, and regional trade agreements, see sources cited in Peter K. Yu, *Intellectual Property and Human Rights in the Nonmultilateral Era*, 64 FLA. L. REV. 1045, 1046 n.1 (2012). For a discussion of intellectual property provisions in international investment agreements, see generally Bryan Mercurio, *Awakening the Sleeping Giant: Intellectual Property Rights in International Investment Agreements*, 15 J. INT’L ECON. L. 871 (2012).

33. As Colin McInnes observed:

Health threats, the provision of health care services and the market for pharmaceuticals are increasingly transborder in nature. In terms of health security, this makes defence ‘at the border’ a near impossibility despite

policymakers and commentators should also think more holistically and globally about the connections between the domestic and international debates and between developments in the intellectual property and public health arenas. After all, there are non-altruistic reasons for developed countries to promote access to essential medicines in the less developed world.

## I. VIRAL PANDEMIC

The first virostory concerns one of the most dreadful viruses of all time: HIV, a virus that results in the development of the yet-to-be curable AIDS.<sup>34</sup> Since its discovery more than three decades ago, AIDS has grown from a disease afflicting only a small portion of the world's population to one having major deleterious effects on an ever-growing number of people. To date, over thirty million adults and about 2.5 million children have been infected with the disease.<sup>35</sup> Another twenty-five million have died owing to the infection.<sup>36</sup> If we count family members, loved ones, and the numerous professionals and volunteers who have cared for the infected, HIV/AIDS has disturbed the lives of an incalculable number of individuals and communities from around the world.

Yet, despite the gravity of this public health crisis and the many dedicated responses, we are still nowhere close to finding a solution to containing, if not curing, the disease. As the Joint United Nations Programme on HIV/AIDS ("UNAIDS") lamented in its 2010 report, about two-thirds of the estimated fifteen million people living with HIV in less

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efforts by states to do just that. The state can no longer function as a self-contained vessel for health provision (and indeed health security), rather it has become permeable. This is most obviously the case with infectious disease where the processes of globalization have enabled disease to spread more quickly.

McInnes, *supra* note 17, at 44 (citation omitted); accord FIDLER, *supra* note 27, at 13–16 (discussing the "germs do not recognize borders" mantra of public health); MARK W. ZACHER & TANIA J. KEEFE, *THE POLITICS OF GLOBAL HEALTH GOVERNANCE: UNITED BY CONTAGION 1* (2008) ("[T]he world is becoming an ever smaller place, and microbes that cause devastating diseases do not stop for border guards.").

34. *But cf.* David Brown, *Baby Born with HIV Is Apparently Cured with Aggressive Drug Treatment*, WASH. POST, Mar. 3, 2013, at A1 (reporting that "[a] baby born with the AIDS virus two years ago in Mississippi who was put on antiretroviral therapy within hours of birth appears to have been cured of the infection").

35. UNAIDS, *GLOBAL REPORT: UNAIDS REPORT ON THE GLOBAL AIDS EPIDEMIC 2010*, at 180 (2010).

36. *Thirty Years of a Disease: The End of AIDS?*, ECONOMIST, June 4, 2011, at 11, available at <http://www.economist.com/node/18774722>.

developed countries have no access to affordable life-saving medications.<sup>37</sup> Such limited access has renewed fears that the disease will continue to plague the globe for decades to come.

Of great importance in the intellectual property arena are issues concerning access to essential medicines—and in this case, access to HIV/AIDS antiretrovirals. The arrival of the TRIPS Agreement in 1994 has greatly curtailed the ability of less developed countries to manufacture affordable generic medicines. Article 27.1, for example, requires WTO member states to offer strong protection of patent rights to “any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”<sup>38</sup> By prohibiting the distinction between patents for pharmaceutical products and patents for processes used to manufacture those products, this provision takes away a key flexibility that some argued has contributed to the successful development of the Indian generic pharmaceutical industry.<sup>39</sup>

Although Article 31 of the TRIPS Agreement allows countries to adopt compulsory licenses under several narrow—and some would say cumbersome—conditions,<sup>40</sup> it has greatly curtailed the ability of these countries to export medicines to less developed countries in need. Article 31(f) specifically limits compulsory licenses to uses “authorized predominantly for the supply of the domestic market.”<sup>41</sup> While countries could still export “a ‘non-predominant’ part of the production,”<sup>42</sup> such export is unlikely to sustain a local generic pharmaceutical industry.

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37. UNAIDS, *supra* note 35, at 7.

38. TRIPS Agreement art. 27.1.

39. See Peter Drahos, *Securing the Future of Intellectual Property: Intellectual Property Owners and Their Nodally Coordinated Enforcement Pyramid*, 36 CASE W. RES. J. INT’L L. 53, 76 (2004) (“India’s success in building a strong pharmaceutical industry was based in large measure upon its recognition of patents for pharmaceutical processes, but not for pharmaceutical products.”).

40. See TRIPS Agreement art. 31 (providing a set of complex procedural rules governing the conditions under which compulsory licenses are to be issued); see also K.M. Gopakumar, *The WTO Deal on Cheap Drugs: A Critique*, 7 J. WORLD INTELL. PROP. 99, 102 (2004) (stating that the procedural formalities required by Article 31 “will result in inordinate delays in the supply of drugs to the importing country”).

41. TRIPS Agreement art. 31(f).

42. Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT’L L. 317, 319 (2005) [hereinafter Abbott, *WTO Medicines Decision*]; accord Communication from the European Communities and Their Member States, *Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health*, ¶ 3, IP/C/W/352 (June 20, 2002) (conceding that Article 31(f) “does . . . allow a non-predominant part of the products concerned to be destined to supply foreign markets (except under the circumstances addressed by Article 31(k))”); F.M. Scherer & Jayashree Watal, *Post-*

As if these restrictions were not significant enough, Article 39.3 of the TRIPS Agreement mandates protection against the unfair commercial use of clinical trial data that have been submitted to regulatory agencies for the approval of pharmaceutical products that utilize new chemical entities.<sup>43</sup> Such protection could make it difficult for pharmaceutical companies to reduce the costs of producing generic drugs by skipping costly clinical trials and conducting bioequivalence studies instead.<sup>44</sup> In recent years, the brand name pharmaceutical industry has relied on Article 39.3 to push for data exclusivity regimes through the negotiation of bilateral, plurilateral, and regional trade agreements.<sup>45</sup> If adopted, these regimes would provide even stronger protection than what is required under the provision.

Given the TRIPS Agreement's significant intrusions on a less developed country's policy space, it is no surprise that intergovernmental organizations and commentators have widely criticized the Agreement for its pernicious effects on the protection of public health. In her highly critical review of the TRIPS Agreement, Mary Robinson, the U.N. High Commissioner for Human Rights, observed:

[T]he overall thrust of the TRIPS Agreement is the promotion of innovation through the provision of commercial incentives. The various links with the subject matter of human rights—the promotion of public health, nutrition, environment and development—are generally expressed in terms of exceptions to

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*TRIPS Options for Access to Patented Medicines in Developing Nations*, 5 J. INT'L ECON. L. 913, 925 (2002) ("The 'predominantly' term in Article 31(f) clearly implies that some exportation under compulsory license in the exporting nation will be allowed."). Interestingly, the African Group proposed to interpret Article 31(f) "to mean that up to 49.9 percent of the production can be exported." Joint Communication from the African Group in the WTO, *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, ¶ 6(d), IP/C/W/351 (June 24, 2002) [hereinafter African Group Proposal].

43. TRIPS Agreement art. 39.3.

44. As the Federal Food, Drug, and Cosmetic Act stated:

A drug shall be considered to be bioequivalent to a listed drug if . . . the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses . . .

21 U.S.C. § 355(j)(8)(B) (2012). Even bioequivalence studies can be quite expensive. For example, "[a] study in Colombia estimated that the requirement of bioequivalence studies for anti-hypertensive and anti-inflammatory drugs would increase the price of domestically manufactured products by a percentage of between 46 and 61 per cent." Joan Rovira, *Creating and Promoting Domestic Drug Manufacturing Capacities: A Solution for Developing Countries*, in NEGOTIATING HEALTH, *supra* note 14, at 227, 234.

45. For discussions of the protection of undisclosed clinical trial data and data exclusivity regimes, see sources cited in Yu, *The International Enclosure Movement*, *supra* note 14, at 895 n.363.

the rule rather than the guiding principles themselves and are made subject to the provisions of the Agreement.<sup>46</sup>

Her report also expressed concern that the Agreement's high international minimum standards and the autonomy it took away could undermine "States' abilities to promote and protect human rights," such as the right to life, the right health, and the right to development.<sup>47</sup> She considered it rather problematic that "the protection contained in the TRIPS Agreement focuses on forms of protection that have developed in industrialized countries."<sup>48</sup>

To be certain, brand name pharmaceutical companies have both the financial and manufacturing capacities to provide affordable medicines to less developed countries. Nevertheless, they rarely do so voluntarily, even if differential pricing—the practice of charging drugs at different prices in different regions, countries, or market segments—could enable them to target both the high- and low-end markets.<sup>49</sup>

There are at least three reasons. First, pharmaceutical companies are concerned that drugs made available at discounted prices would flow back as parallel imports to their developed country markets, such as the United States or members of the European Union.<sup>50</sup> In recent years, these companies have worked closely with governments to close down online pharmacies, which they claimed were selling unsafe and sub-standard drugs.<sup>51</sup>

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46. High Commissioner for Human Rights, *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, Sub-Comm'n on the Promotion and Prot. of Human Rights, ¶ 22, U.N. Doc. E/CN.4/Sub.2/2001/13 (June 27, 2001) [hereinafter *High Commissioner's Report*].

47. *Id.* ¶ 24.

48. *Id.* ¶ 25.

49. See generally Patricia M. Danzon & Adrian Towse, *Theory and Implementation of Differential Pricing for Pharmaceuticals*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 425 (Keith E. Maskus & Jerome H. Reichman eds., 2005) [hereinafter INTERNATIONAL PUBLIC GOODS] (discussing differential pricing).

50. See Keith E. Maskus, *Ensuring Access to Essential Medicines: Some Economic Considerations*, 20 WIS. INT'L L.J. 563, 566–67 (2002) [hereinafter Maskus, *Ensuring Access to Essential Medicines*] ("There are concerns that if medicines were offered to poorer patients at lower prices the drugs could be resold in the higher-priced segment of the market."). "While arbitrage is often cited as a factor preventing differential pricing, the real magnitude of the concern must be kept in perspective. Large pharmaceutical companies understand the problems of arbitrage and know how to take appropriate safeguards." Peter J. Hammer, *Differential Pricing of Essential AIDS Drugs: Markets, Politics and Public Health*, 5 J. INT'L ECON. L. 883, 889 n.10 (2002). The August 30 Decision, for example, requires products produced under a Paragraph 6 license to be "clearly identified as being produced under the system set out in this Decision through specific labelling or marking." August 30 Decision, *supra* note 26, ¶ 2(b)(ii).

51. See, e.g., Press Release, Pharm. Research and Mfrs. of Am., PhRMA Commends the Administration for Increased Attention to Worldwide Counterfeit Medicine Threat (Mar. 11,

Second, pharmaceutical companies fear that the price concessions they make in less developed countries would reveal the marginal costs of drug production. Such revelation, in turn, could result in public or governmental pressure in developed country markets, calling for lower drug prices for at least low-income households.<sup>52</sup> In addition, the use of “reference pricing”—that is, price controls based on an index of prices in comparison countries—by health authorities in some developed countries has made pharmaceutical companies reluctant to set lower prices in the less developed world.<sup>53</sup>

Third, because wealth is usually distributed very unevenly in many less developed countries—South Africa being a notorious example—some pharmaceutical companies choose to sell their products at high prices that are affordable by the “more affluent minority,” even if those prices would make the products unaffordable to the larger and poorer majority.<sup>54</sup> Given

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2011), available at <http://www.phrma.org/media/releases/phrma-commends-administration-increased-attention-worldwide-counterfeit-medicine-thre> (“[T]he U.S. government’s renewed emphasis on collaboration, information sharing, education and enforcement—as it relates to counterfeit pharmaceuticals—is warmly welcomed. The role of the Intellectual Property Enforcement Coordinator in shaping this strategic, comprehensive, organized and coordinated U.S. government response to combating counterfeit medicines internationally cannot be understated.”). Nevertheless, it is important to distinguish between counterfeit and sub-standard drugs. While counterfeit drugs are sold in violation of intellectual property laws, sub-standard drugs fail to meet the stated quality, safety, or efficacy standards. Because of the very different focus, counterfeit drugs can be sub-standard, but not all counterfeit drugs are sub-standard. See Peter K. Yu, *Enforcement, Economics and Estimates*, 2 WIPO J. 1, 12 (2010) (“Policymakers and industry representatives have a high tendency to equate pirated or counterfeit products with sub-standard goods. However, this tendency is somewhat misguided.” (footnote omitted)); see also Li Xuan, *Ten General Misconceptions About the Enforcement of Intellectual Property Rights*, in INTELLECTUAL PROPERTY ENFORCEMENT: INTERNATIONAL PERSPECTIVES 14, 20–21 (Li Xuan & Carlos M. Correa eds., 2009) [hereinafter INTELLECTUAL PROPERTY ENFORCEMENT] (discussing the misconception that counterfeit and piracy always pose a consumer threat).

52. See Frederick M. Abbott, *The Cycle of Action and Reaction: Developments and Trends in Intellectual Property and Health*, in NEGOTIATING HEALTH, *supra* note 14, at 27, 29 [hereinafter Abbott, *Cycle of Action*]; see also Hammer, *supra* note 50, at 893–94 (“[E]ven without the threat of physical arbitrage, implicitly revealing information in the very act of setting lower prices in developing countries could lead to an unravelling of high prices in developed countries.”).

53. See Maskus, *Ensuring Access to Essential Medicines*, *supra* note 50, at 567 (“In a reference pricing system, price controls in one country are based on an index of prices in comparison countries. To the extent that the comparison group includes developing economies, firms may prefer not to offer price discounts there.”).

54. See Danzon & Towse, *supra* note 49, at 455 (“[P]ricing in some [developed countries] is dominated by the demands of small, affluent populations, resulting in prices that are unaffordable to the majority of poorer people.”); Sean Flynn et al., *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 37 J.L., MED. & ETHICS 184, 185 (2009) (“[I]n countries with very high income inequality, which characterizes many developing countries, market forces may produce incentives for patent holders to maximize profits by pricing their products to serve only the wealthiest sliver of the

the certainty in the affluent market and the efficiency generated by strategies targeting comparable customers, it is understandable why many pharmaceutical companies would find the affluent market more attractive.<sup>55</sup> Based on these three reasons, brand name pharmaceutical companies have limited interest in providing affordable drugs to less developed countries, despite their considerable demand for these drugs.

To meet this demand, less developed countries have sought solutions elsewhere. Although the TRIPS Agreement has greatly strengthened patent protection, it includes transition periods for developing and least developed countries,<sup>56</sup> technology transfer provisions,<sup>57</sup> explicit health-related

population.”); F.M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries* 45 (Comm’n on Macroeconomics & Health, Working Paper No. WG4:1, 2001), cited in Yu, *The International Enclosure Movement*, *supra* note 14, at 844 n.75 (advancing the concept of the “more affluent minority”). As Sean Flynn, Aidan Hollis, and Mike Palmedo explained:

Income inequality exists to a greater or lesser extent in every developing country, where a small minority often earns salaries that compare to those of advanced industrialized countries and the majority live in poverty. This inequality creates incentives for an unrestrained monopoly supplier ineluctably to set drugs prices high. The problem is that relatively rich people, though few, are able to pay so much more for their drugs that it is more profitable for a company to serve them only. The greater the inequality of the income or wealth distribution, the more severe this problem becomes, with greater individual ability to pay on the part of the very rich pushing the price up.

Flynn et al., *supra*, at 190 (footnote omitted).

55. See Maskus, *Ensuring Access to Essential Medicines*, *supra* note 50, at 566 (“[P]harmaceutical firms and their distributors in poor countries may find it more profitable to sell drugs in low volumes and high prices to wealthier patients with price-inelastic demand rather than in high volumes at low prices to poorer patients.”).

56. See TRIPS Agreement arts. 65–66.1 (providing transition periods for developing, transition, and least developed countries).

57. See *id.* art. 7 (“The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”); *id.* art. 66.2 (requiring developed countries to “provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base”); *id.* art. 67 (requiring developed countries to “provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members”); see also WTO, *Implementation-Related Issues and Concerns: Decision of 14 November 2001*, ¶ 11.2, WT/MIN(01)/17 (Nov. 20, 2001) (stating that “the provisions of Article 66.2 of the TRIPS Agreement are mandatory”). Sadly, despite the explicit language in these provisions and the WTO’s recent affirmation of the mandatory nature of the technology transfer obligations under Article 66.2, “developed countries thus far have only paid lip service to these obligations, with some undoubtedly subscribing to the view that these obligations are merely aspirational.” Peter K. Yu, *TRIPS and Its Achilles’ Heel*, 18 J. INTELL. PROP. L. 479, 526 (2011).



safeguards,<sup>58</sup> and a number of other flexibilities.<sup>59</sup> A key flexibility is Article 31, which allows countries to provide compulsory licenses under very restrictive conditions.<sup>60</sup> Although developed countries often criticize less developed countries for using compulsory licenses, those licenses are available in many developed countries,<sup>61</sup> including both the United States<sup>62</sup> and members of the European Union.

Thus far, few less developed countries dared to ignore external pressure to issue compulsory licenses in the pharmaceutical area.<sup>63</sup> Brazil is

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58. See, e.g., TRIPS Agreement art. 8.1 ("Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition . . . , provided that such measures are consistent with the provisions of this Agreement."); *id.* art. 27.2 ("Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health . . . , provided that such exclusion is not made merely because the exploitation is prohibited by their law.").

59. See Yu, *The International Enclosure Movement*, *supra* note 14, at 863–66 (discussing the various flexibilities available in the TRIPS Agreement).

60. TRIPS Agreement art. 31.

61. See IPR COMMISSION REPORT, *supra* note 29, at 42 ("Canada used compulsory licensing extensively in the pharmaceutical field from 1969 until the late 1980s. This resulted in prices of licensed drugs being 47% lower than in the US in 1982. The UK also used compulsory licensing until the 1970's, including for important drugs such as Librium and Valium." (footnote omitted)); James Love, *Access to Medicine and Compliance with the WTO TRIPS Accord: Models for State Practice in Developing Countries*, in GLOBAL INTELLECTUAL PROPERTY RIGHTS: KNOWLEDGE, ACCESS AND DEVELOPMENT 74, 81–83 (Peter Drahos & Ruth Mayne eds., 2002) (discussing the government use provisions in the United States, Italy, Australia, Germany, Malaysia, Singapore, New Zealand, the Philippines, Ireland, Switzerland, and the United Kingdom); Yu, *The International Enclosure Movement*, *supra* note 14, at 845 ("[C]ompulsory licensing has been widely used throughout the world, including by such developed countries as Canada, the United Kingdom, and the United States.").

62. See 28 U.S.C. § 1498(a) (2012) (allowing the government and its contractors to use patented items in return for compensation through a proceeding before the United States Court of Federal Claims); see also Frederick M. Abbott, *Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines*, in INTERNATIONAL PUBLIC GOODS, *supra* note 49, at 393, 412 ("No country facilitates government use of patents better than the United States."); Ragavan, *Jekyll and Hyde*, *supra* note 17, at 796–812 (discussing the United States' use of compulsory licensing and price control mechanisms under circumstances less threatening than national emergencies).

63. See ELLEN F.M. 'T HOEN, *THE GLOBAL POLITICS OF PHARMACEUTICAL MONOPOLY POWER: DRUG PATENTS, ACCESS, INNOVATION AND THE APPLICATION OF THE WTO DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH* 44–59 (2009) (discussing the use of compulsory licensing arrangements in Brazil, Thailand, Malaysia, South Africa, Kenya, and India); Jonathan Burton-MacLeod, *Tipping Point: Thai Compulsory Licences Redefine Essential Medicines Debate*, in INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES 406 (Thomas Pogge et al. eds., 2010) [hereinafter INCENTIVES FOR GLOBAL PUBLIC HEALTH] (discussing Thailand's use of compulsory licenses to promote access to essential medicines); Elizabeth Siew-Kuan Ng, *Global Health and Development: Patents and Public Interest*, in INCENTIVES FOR GLOBAL PUBLIC HEALTH, *supra*, at 101, 120 ("Thailand's use of compulsory licensing in relation to antiretroviral drugs for HIV/AIDS, cancer and heart disease

generally considered the poster child for using—or, more precisely, threatening to use—compulsory licenses to obtain concessions from brand name pharmaceutical companies.<sup>64</sup> As Pedro Roffe noted, “[w]hile the [Brazilian] Government never issued a compulsory licence, it managed to use the mere threat of issuing one to reduce the price of individual HIV/AIDS retroviral drugs by up to 75 per cent.”<sup>65</sup> Notwithstanding its success, Brazil does not provide a good model for other less developed countries. Many conditions in that country cannot be replicated in other parts of the less developed world.

First, the significant productive capacity in the public sector in Brazil “allowed the country to make the threat of compulsory licensing credible and, as a consequence, gave it a strong negotiating capacity for obtaining low prices from patent holders.”<sup>66</sup> Having indigenous productive capacity is important because a country cannot force pharmaceutical companies to export drugs against their wishes or devote resources to develop treatments for diseases that primarily affect its population.<sup>67</sup>

Second, Brazil contains a lucrative middle class market that U.S. pharmaceutical companies cannot afford to lose or alienate. Compared with other less developed countries, Brazil “is less dependent on the U.S. for . . . a market for its own exported products.”<sup>68</sup> Its large, profitable domestic market has enabled the development and sustenance of a local generic

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. . . has precipitated similar calls from other developing countries, such as India and the Philippines, for the urgent need to lower the cost of medicines and make them more affordable to sufferers.”).

64. See, e.g., IPR COMMISSION REPORT, *supra* note 29, at 43 (providing the Brazilian National STD/AIDS Program as an illustration); Ellen ‘t Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT’L L. 27, 32 (2002) [hereinafter ‘t Hoen, *TRIPS, Pharmaceutical Patents*] (stating that “[t]he Brazil AIDS program serves as a model for some developing countries that are able to produce medicines locally”).

65. Pedro Roffe with Christoph Spennemann & Johanna von Braun, *From Paris to Doha: The WTO Doha Declaration on the TRIPS Agreement and Public Health*, in *NEGOTIATING HEALTH*, *supra* note 14, at 9, 15; see also Karin Timmermans, *Ensuring Access to Medicines in 2005 and Beyond*, in *NEGOTIATING HEALTH*, *supra* note 14, at 41, 46 (noting that strategies seeking voluntary licenses at reasonable royalty rates “are bound to be most successful when they are backed up by a realistic ‘threat’ to use TRIPS safeguards or competition laws”).

66. Rovira, *supra* note 44, at 236.

67. Theoretically, countries could nationalize foreign pharmaceutical firms, if those firms were already present in the country. In reality, however, such action is highly undesirable, because it could only be used once. In the long run, it would also hurt the country more than it would help. See Peter K. Yu, *Access to Medicines, BRICS Alliances, and Collective Action*, 34 AM. J.L. & MED. 345, 358–59 (2008) [hereinafter Yu, *Access to Medicines*].

68. Eyal Benvenisti & George W. Downs, *Distributive Politics and International Institutions: The Case of Drugs*, 36 CASE W. RES. J. INT’L L. 21, 44 (2004).

pharmaceutical industry, which, in turn, could benefit from the economies of scale and scope created by that market.<sup>69</sup>

Third, Brazil has the right conditions and infrastructure to manufacture drugs. As a World Health Organization (“WHO”) document noted:

The complex process of pharmaceutical production . . . requires special technologies, reliable supplies of high-quality raw materials, and dependable provision of top-quality water, electricity, gas and other utilities. It also needs sufficient human resources with specialist knowledge, such as experts in pharmaceutical development, quality assurance and regulatory processes. Even for generic drugs, some research and development is necessary for the manufacture of high-quality products, and the expenses and time incurred are often underestimated. Pharmaceutical plants need a huge initial capital outlay and take many years to construct; they tend to be located in countries with a good infrastructure, reliable utilities and access to technical expertise.<sup>70</sup>

Thus, unlike Brazil, a lot of less developed countries, including virtually all of those in the least developed world, have neither the ability nor the leverage to use Article 31 of the TRIPS Agreement to convince brand name pharmaceutical companies to reduce drug prices.<sup>71</sup> Even worse, Article

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69. See Communication from the Permanent Mission of Brazil, *Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health*, ¶ 12, IP/C/W/355 (June 24, 2002) (noting that “economies of scale that would reduce costs of production and thus provide more affordable prices for . . . countries in situations . . . where domestic production in small quantities from a compulsory licence for a particularly high-priced product may be impractical or too costly”); Rovira, *supra* note 44, at 229 (pointing out that a limited market size “might make unprofitable a local industry restricted to the domestic market”); Yu, *The International Enclosure Movement*, *supra* note 14, at 848 (“Because the markets in less developed countries are very small, it may be virtually unprofitable to develop a local industry that is primarily restricted to the domestic market.”).

70. WHO Executive Board, *Manufacture of Antiretrovirals in Developing Countries and Challenges for the Future*, ¶ 2, WHO Doc. EB114/15 (Apr. 29, 2004), available at [http://apps.who.int/iris/bitstream/10665/20177/1/B114\\_15-en.pdf](http://apps.who.int/iris/bitstream/10665/20177/1/B114_15-en.pdf); see Rovira, *supra* note 44, at 231 (“Few developing and emerging countries have the capacity to produce [active pharmaceutical ingredients]. Those who can include India, China, Thailand, Egypt, Brazil, Mexico, Argentina and, to some extent, Yugoslavia and Turkey.”); Timmermans, *supra* note 65, at 42 (noting that “Indian companies are major suppliers of generic medicines and of the active pharmaceutical ingredients . . . necessary for their production to other developing and developed countries”).

71. See N. Lalitha, *Access to Indian Generic Drugs: Emerging Issues*, in INTELLECTUAL PROPERTY, PHARMACEUTICALS, AND PUBLIC HEALTH: ACCESS TO DRUGS IN DEVELOPING COUNTRIES 225, 225 (Kenneth C. Shadlen et al. eds., 2012) (“Globally, about 60 developing countries have no pharmaceutical industry and 87 have capacity to make finished products only.”).

31(f), which states that compulsory licenses can only be issued “predominantly for the supply of the domestic market,”<sup>72</sup> prevented third countries, such as India, from exporting affordable generic drugs to these countries.

At the Fourth Ministerial Conference in Doha in November 2001, before the expiration of the transition period concerning pharmaceutical products, less developed countries successfully negotiated for the adoption of the Doha Declaration on the TRIPS Agreement and Public Health (“Doha Declaration”).<sup>73</sup> The opening paragraph of this Declaration explicitly “recognize[d] the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”<sup>74</sup> Paragraph 2 underscored “the need for the [TRIPS Agreement] to be part of the wider national and international action to address these problems.”<sup>75</sup> Paragraph 4 declared that member states “agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health” and that “the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.”<sup>76</sup> Paragraph 5 underscored the various “flexibilities” reserved to all WTO member states under the TRIPS Agreement.<sup>77</sup> Paragraph 6 “recognize[d] that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of

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72. TRIPS Agreement art. 31(f).

73. WTO, Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration]. While less developed countries certainly have made a strong case for adjustment needs, their success should also be attributed to the momentum generated from the brand name pharmaceutical industry’s debacle in South Africa, the United States’ eagerness to launch a new round of trade negotiation following the September 11 terrorist attacks, and the access-to-medicines challenges created by the anthrax attacks in the Canada and the United States. See Louise Amoore et al., *Series Preface* to AMRITA NARLIKAR, INTERNATIONAL TRADE AND DEVELOPING COUNTRIES: BARGAINING COALITIONS IN THE GATT & WTO xiii, xiii (2003) (noting that the launch of the Doha Round was “assisted to a large degree by the conciliatory international political climate that followed the September 2001 terrorist attacks in New York and Washington”); Yu, *The International Enclosure Movement*, *supra* note 14, at 874 n.247 (providing sources discussing how the United States’ responses to high prices of ciprofloxacin following the anthrax attacks have undermined its own position against compulsory licensing).

74. Doha Declaration, *supra* note 73, ¶ 1.

75. *Id.* ¶ 2.

76. *Id.* ¶ 4.

77. *Id.* ¶ 5; see also Abbott, *Cycle of Action*, *supra* note 52, at 27, 30 (highlighting the various flexibilities less developed countries retain in the public health arena despite the entering into force of the TRIPS Agreement).

compulsory licensing under the TRIPS Agreement.”<sup>78</sup> Finally, Paragraph 7 delayed the introduction of protection for pharmaceutical patents and undisclosed clinical trial data until January 1, 2016.<sup>79</sup>

Out of all the seven paragraphs, Paragraph 6 was the most important to developing and least developed countries. Pursuant to this paragraph, the TRIPS Council adopted the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health on August 30, 2003.<sup>80</sup> Shortly before the Sixth WTO Ministerial Conference in Hong Kong in 2005, this decision was formalized as the proposed Article 31*bis* of the TRIPS Agreement.<sup>81</sup> If ratified by two-thirds of the WTO membership, this amendment would allow countries with insufficient or no manufacturing capacity to import generic versions of patented pharmaceuticals.

Since the adoption of this protocol, the ratification deadline has been extended four times already—from December 2007 to December 2015.<sup>82</sup> As of this writing, less than a third of the 159 WTO member states, including mostly high- and middle-income countries, have ratified the proposed amendment. However, and tellingly, many countries in Sub-Saharan Africa, the key targets of this amendment, have yet to ratify the document (see Table 1).

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78. Doha Declaration, *supra* note 73, ¶ 6.

79. *Id.* ¶ 7.

80. August 30 Decision, *supra* note 26.

81. TRIPS Amendment, *supra* note 24.

82. See *supra* text accompanying notes 25–26.

2005–2007	2008–2009	2009–2011	2011–2013
United States	Mauritius	Nicaragua	Togo
Switzerland	Egypt	Pakistan	Saudi Arabia
El Salvador	Mexico	Former Yugoslav	Chinese Taipei
Republic of Korea	Jordan	Republic of	Dominican
Norway	Brazil	Macedonia	Republic
India	Morocco	Uganda	Chile
Philippines	Albania	Mongolia	Montenegro
Israel	Macau, China	Croatia	Trinidad and
Japan	Canada	Senegal	Tobago
Australia	Bahrain	Bangladesh	
Singapore	Colombia	Argentina	
Hong Kong, China	Zambia	Indonesia	
China		New Zealand	
European Union		Cambodia	
		Panama	
		Costa Rica	
		Rwanda	
		Honduras	

**Table 1. WTO Members Accepting the Article 31*bis* Amendment  
(As of October 1, 2013)<sup>83</sup>**

While less developed countries were busy considering and pushing for the ratification of this amendment, commentators have greatly criticized the amendment for being “unduly cumbersome and complex.”<sup>84</sup> They have

83. *Members Accepting Amendment*, *supra* note 25.

84. Timmermans, *supra* note 65, at 45; accord Carlos M. Correa, *Recent International Developments in the Area of Intellectual Property Rights* 4, [http://www.iprsonline.org/unctadictsd/bellagio/docs/Correa\\_Bellagio2.pdf](http://www.iprsonline.org/unctadictsd/bellagio/docs/Correa_Bellagio2.pdf) (last visited Mar. 2, 2013) [hereinafter Correa, *Recent International Developments*] (“The adopted ‘solution’ is so cumbersome for potential suppliers that they will be hardly encouraged to use the Decision, ‘because it is so designed that no generic manufacturer would be able or willing to comply with its provisions.’” (footnote omitted) (quoting D.G. Shah, Indian Pharmaceutical Alliance)); Gopakumar, *supra* note 40, at 106 (stating that “the [August 30] Decision has opted for a cumbersome route, ignoring a simple solution under Article 30 of TRIPS”); Andrew D. Mitchell

expressed concern about the amendment's failure to address the transfer of pharmaceutical technology to less developed countries.<sup>85</sup> In addition, they were disturbed by the countries' inability to "prevent a private party from blocking the exportation or importation of drugs, if the national laws do not specifically permit such exports or imports under compulsory licenses."<sup>86</sup> As Jorge Bermudez, Maria Oliveira, and Gabriela Chaves lamented, "[p]oor countries of Africa, Asia, and Latin America have to go through unnecessary red tape to prove that they do not have manufacturing capacity."<sup>87</sup> Matthew Rimmer went even further to note that "[t]he codification of such a flawed model would only exacerbate the public health

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& Tania Voon, *The TRIPS Waiver as a Recognition of Public Health Concerns in the WTO*, in INCENTIVES FOR GLOBAL PUBLIC HEALTH, *supra* note 63, at 56, 71 (criticizing the TRIPS waiver for "not affect[ing] Article 31(b) of the TRIPS Agreement, which usually requires the proposed user to attempt to obtain an ordinary commercial licence from the right holder, potentially involving lengthy negotiations" and for the difficulty in "determin[ing] in advance precisely how much of a given product will be needed in a given country"). *But see* Tenu Avafia et al., *The Ability to Utilize TRIPS Flexibilities in Sub-Saharan African Countries*, in INTELLECTUAL PROPERTY AND SUSTAINABLE DEVELOPMENT: DEVELOPMENT AGENDAS IN A CHANGING WORLD 175, 200 (Ricardo Meléndez-Ortiz & Pedro Roffe eds., 2010) ("[T]he lack of use of the 30 August Agreement mechanism does not mean that this Agreement has been entirely unsuccessful. The express authorization of countries to import generic essential medicines must have been a factor, together with others, for the increased number of voluntary licenses that have been granted by patent-holding companies in the past few years."); Wolfgang Hein, *Global Health Governance and WTO/TRIPS: Conflicts Between "Global Market-Creation" and "Global Social Rights,"* in FIGHT AGAINST HIV/AIDS, *supra* note 17, at 38, 56 ("Although until today we cannot observe an increased use of compulsory licences by developing countries, experts do agree that [the] legal and political strengthening [provided by the August 30 decision and the proposed TRIPS amendment] has given developing countries a stronger position in conflicts with [transnational pharmaceutical companies] on licences and price concessions."); Mitchell & Voon, *supra*, at 72 ("[A]ttempting to operationalize [the TRIPS waiver] while working around its flaws is preferable to discarding it altogether and hoping for a better solution to emerge from the WTO in the near future."); Yu, *The International Enclosure Movement*, *supra* note 14, at 877 (stating that "the [TRIPS] waivers, on balance, represented a promising first step in focusing attention on the public health crises in less developed countries and in reclaiming some of their lost policy space").

85. See M. Rafiqul Islam, *The General Drug Deal of the WTO from Doha to Cancun: A Peripheral Response to a Perennial Conundrum*, 7 J. WORLD INTELL. PROP. 675, 692 (2004).

86. Correa, *Recent International Developments*, *supra* note 84, at 3 (emphasis omitted).

87. Jorge A.Z. Bermudez et al., *Intellectual Property in the Context of the WTO TRIPS Agreement: What Is at Stake?*, in INTELLECTUAL PROPERTY IN THE CONTEXT OF THE WTO TRIPS AGREEMENT: CHALLENGES FOR PUBLIC HEALTH 23, 56 (Jorge A.Z. Bermudez & Maria Auxiliadora Oliveira eds., 2004); *see also* Abbott, *WTO Medicines Decision*, *supra* note 42, at 353 ("Ambiguous pharmaceutical-related rules raise serious problems when procurement officials try to do their work.").

crisis in developing countries caused by infectious diseases, such as HIV/AIDS, tuberculosis and malaria.”<sup>88</sup>

Empirically, these critiques have been strongly supported by the fact that only one country has ever used the proposed arrangement to send drugs from a developed country to a less developed country. In September 2008, Apotex, a Canadian generic manufacturer, made its first shipment of the HIV/AIDS drug TriAvir to Rwanda through the Canada’s Access to Medicine Regime<sup>89</sup>—one of the very few regimes introduced at the national level to implement the TRIPS waiver.<sup>90</sup> Although Apotex was eventually able to deliver the drugs after going through the process for three years, it expressed strong reluctance to use the arrangement again, citing bureaucratic barriers and the time-consuming process. As Jack Kay, Apotex’s president, declared:

We invested millions in the research and development of the product, legal costs in negotiating with the brand companies and made no profits in this process. We did it because it was the right thing to do. But in its current form it’s not workable for us and, it appears, it doesn’t work easily for developing countries.<sup>91</sup>

To some extent, the highly cumbersome arrangement can be compared to the equally cumbersome arrangement in the Appendix to the Berne Convention.<sup>92</sup> Adopted out of a compromise between developed and less

88. Matthew Rimmer, *Race Against Time: The Export of Essential Medicines to Rwanda*, 1 PUB. HEALTH ETHICS 89, 100 (2008).

89. See Mitchell & Voon, *supra* note 84, at 69. For discussions of Apotex’s shipments and challenges, see HO, *supra* note 14, at 214–17; *Last Cheaper AIDS Medicines for Rwanda Under WTO*, INTELL. PROP. WATCH (Sept. 17, 2009, 10:52 PM), <http://www.ip-watch.org/weblog/2009/09/17/last-cheaper-aids-medicines-for-rwanda-under-wto/>.

90. See UNAIDS, *Implementation of TRIPS and Access to Medicines for HIV After January 2016: Strategies and Options for Least Developed Countries* 8 (UNAIDS, Technical Brief, 2011), [http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2258\\_techbrief\\_TRIPS-access-medicines-LDC\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2258_techbrief_TRIPS-access-medicines-LDC_en.pdf) [hereinafter *UNAIDS Technical Brief*] (“So far, only Canada, countries in the European Community, and India have put in place the system to allow the functioning of the 30 August 2003 decision.”); see also Mitchell & Voon, *supra* note 84, at 70 (“The US . . . was first to accept the Protocol in 2005 but has still not implemented corresponding legislation.”). See generally Kristina M. Lybecker & Elisabeth Fowler, *Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules*, 37 J.L., MED. & ETHICS 222 (2009) (discussing Canada’s Access to Medicine Regime).

91. Press Release, Apotex, CAMR Federal Law Needs to Be Fixed If Life-Saving Drugs for Children Are to Be Developed (May 14, 2009), <http://www.apotex.com/global/about/press/20090514.asp>.

92. Berne Convention for the Protection of Literary and Artistic Works app., Sept. 9, 1886, 25 U.S.T. 1341, 828 U.N.T.S. 221 (revised at Paris July 24, 1971); see also SAM RICKETSON & JANE C. GINSBURG, *INTERNATIONAL COPYRIGHT AND NEIGHBORING RIGHTS: THE BERNE CONVENTION AND BEYOND* 960–63 (2d ed. 2005) (discussing the incorporation of the



developed countries, this Appendix permits unauthorized, compensated uses of copyrighted works, including educational texts, scientific books, and other nonfictional works. The Berne Appendix has since been incorporated by reference into the TRIPS Agreement and the WIPO Copyright Treaty.<sup>93</sup> Although the Appendix was created to facilitate access to copyrighted content in less developed countries,<sup>94</sup> its cumbersome and highly bureaucratic nature has made the process virtually unusable by target beneficiaries.<sup>95</sup> Ruth Okediji declared the Appendix “a dismal failure,”<sup>96</sup> while Alan Story suggested we “burn” the Berne Convention.<sup>97</sup>

Even more problematic for many less developed countries, new issues have arisen just as the international intellectual property system began to show greater appreciation of the need to promote access to essential medicines. For example, the proliferation of bilateral and regional trade agreements have introduced provisions calling for the establishment of a data exclusivity regime to protect clinical trial data submitted during the

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Berne Appendix into the TRIPS Agreement and the WIPO Copyright Treaty); Peter K. Yu, *A Tale of Two Development Agendas*, 35 OHIO N.U. L. REV. 465, 481–84 (2009) [hereinafter Yu, *Two Development Agendas*] (discussing the Berne Appendix).

93. See TRIPS Agreement art. 9.1; WIPO Copyright Treaty art. 1, adopted Dec. 20, 1996, S. Treaty Doc. No. 105-17, at 1 (1997).

94. See Ruth L. Okediji, *The International Copyright System: Limitations, Exceptions and Public Interest Considerations for Developing Countries* 16 (Int’l Ctr. for Trade & Sustainable Dev., Issue Paper No. 15, 2006), available at [http://www.unctad.org/en/docs/iteipc200610\\_en.pdf](http://www.unctad.org/en/docs/iteipc200610_en.pdf) [hereinafter Okediji, *International Copyright System*] (stating that the Berne Appendix “remains the only bulk access mechanism tool in international copyright law”).

95. See Ndéné Ndiaye, *The Berne Convention and Developing Countries*, 11 COLUM.-VLA J.L. & ARTS 47, 55 (1986) (“The provisions of the Appendix enable the developing countries neither to ‘make the application of the Convention easier’ nor to meet their needs with regard to education. Indeed, it is certainly easier to understand and to apply the substantive provisions (Articles 1 to 20) than to implement the mechanisms provided for in the Appendix.”); Yu, *Two Development Agendas*, *supra* note 92, at 482–83 (discussing the cumbersome conditions one has to satisfy before a compulsory license can be issued for “teaching, scholarship, and research” purposes).

96. Ruth L. Okediji, *Fostering Access to Education, Research and Dissemination of Knowledge Through Copyright* 9, available at [http://www.iprsonline.org/unctadictsd/bellagio/docs/Okideiji\\_Bellagio4.pdf](http://www.iprsonline.org/unctadictsd/bellagio/docs/Okideiji_Bellagio4.pdf); see also RICKETSON & GINSBURG, *supra* note 92, at 957 (“[O]f those countries that have made the necessary declarations, very few actually seem to have implemented such licensing schemes in their domestic laws.”); Okediji, *International Copyright System*, *supra* note 94, at 15–16 (“As of 2004, only thirteen . . . countries had expressed an interest to WIPO, though Singapore apparently expressed an interest and then didn’t renew its notification.” (footnote omitted)).

97. Alan Story, *Burn Berne: Why the Leading International Copyright Convention Must Be Repealed*, 40 HOUS. L. REV. 763, 763 (2003) (advocating the repeal of the Berne Convention).

regulatory approval process,<sup>98</sup> the linkage of the registration of pharmaceutical products to their patent status,<sup>99</sup> and the requirement that patents be granted for “new uses,” or second indications, of known compounds.<sup>100</sup> Developed countries also actively negotiated plurilateral agreements, such as the recently-adopted ACTA and the still-incomplete TPP. Commentators have generally expressed concerns about the potential of these agreements for aggravating the access-to-medicines crisis in the less developed world.<sup>101</sup>

As if the proliferation of these agreements were not enough, many less developed countries fear that the end of the transition period for pharmaceuticals would induce India to switch over from the generic model to the proprietary model.<sup>102</sup> Such a switch would therefore greatly reduce

98. See, e.g., CAFTA-DR, *supra* note 32, art. 15.10.1; AUSFTA, *supra* note 32, art. 17.10.1; SUSFTA, *supra* note 32, art. 16.8.1.

99. See, e.g., CAFTA-DR, *supra* note 32, art. 15.10.2; AUSFTA, *supra* note 32, art. 17.10.4; SUSFTA, *supra* note 32, art. 16.8.4. See generally Carlos M. Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT'L L. 79, 88–91 (2004) [hereinafter Correa, *Bilateralism in Intellectual Property*] (discussing patent-registration linkage). As Professor Correa noted:

The patent-registration linkage ignores that patents are private rights, as stated in the Preamble of the TRIPS Agreement, and that, whether a given product infringes or not, a patent is a legal matter entirely separate from the technical issues concerning safety and efficacy of drugs. Health authorities have no knowledge or experience whatsoever to assess the claims of a patent.

*Id.* at 89. Professor Correa also criticized the patent registration linkage for “creat[ing] a presumption of validity of pharmaceutical product patents which health authorities are neither empowered nor have the capacity to challenge.” *Id.* at 91.

100. See, e.g., AUSFTA, *supra* note 32, art. 17.9.1; U.S.-Bahrain Free Trade Agreement, U.S.-Bahr., art. 14.8.2, Sept. 14, 2004, available at <http://www.ustr.gov/trade-agreements/free-trade-agreements/bahrain-fta/final-text>. Cf. Abbott, *Cycle of Action*, *supra* note 52, at 30 (“The TRIPS Agreement does not specify that new-use patents must be granted.”); Correa, *Bilateralism in Intellectual Property*, *supra* note 99, at 82 (“[WTO m]embers have considerable discretion in defining this concept, which excludes second indications, new formulations, or dosage forms.”).

101. For discussions of ACTA’s impact on access to medicines, see generally Brook K. Baker, *ACTA—Risks of Third-Party Enforcement for Access to Medicines*, 26 AM. U. INT’L L. REV. 579 (2011); Sean Flynn & Bijan Madhani, *ACTA and Access to Medicines*, THE GREENS: EUROPEAN FREE ALLIANCE (Oct. 6, 2011), <http://rfc.act-on-acta.eu/access-to-medicines>.

102. See ‘T HOEN, *supra* note 63, at 37 (“[I]t is to be expected that the Indian generic medicines sector will shift its business orientation away from supplying new medicines to the developing world, and towards the export of off-patent generics to more affluent markets.”); Peter K. Yu, *The Global Governance of HIV/AIDS and the Rugged Road Ahead: An Epilogue*, in GLOBAL GOVERNANCE OF HIV/AIDS, *supra* note 16, at 223, 227–28 [hereinafter Yu, *Rugged Road Ahead*] (“[W]ith the expiry of the transitional periods allowed for developing countries under the TRIPS Agreement, it is unclear whether India, Brazil, China, Thailand and other countries with the capacity to manufacture generic antiretrovirals will still be interested in meeting the demands of countries lacking in such capacity.”); UNAIDS/UNDP *Issue Brief*,

the supply of much-needed generic pharmaceuticals. As Kenneth Shadlen observed:

The Doha Declaration (and much of the writing on this topic) makes a distinction between the challenges facing developing countries with sufficient local manufacturing capabilities and those without. Yet as significant as some developing countries' manufacturing capacity may be, even the largest developing countries (e.g., Brazil) are heavily dependent on ARVs produced in India. Thus the more appropriate distinction is between ARV-exporters and ARV-importers (or to be blunt, India and not India).<sup>103</sup>

Because India is such an important supplier of generic drugs to the less developed world, the model its industry embraces is likely to have significant ramifications for countries in need of affordable medicines.

During the ACTA negotiations, stories about the seizure of pharmaceuticals in Europe have raised important questions about the intellectual property enforcement standards set in the TRIPS Agreement and the handling of in-transit goods under the General Agreement on Tariffs and Trade.<sup>104</sup> The issues were so contentious that India and Brazil filed complaints before the WTO Dispute Settlement Body against the European Union and the Netherlands over the repeated seizure of in-transit generic

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*supra* note 22, at 5 (noting the “declining certainty that [least developed countries] will be able to continue importing cheap generic medicines”); *see also* Biswajit Dhar & K.M. Gopakumar, *The Case of the Generic Industry in India*, in *INTELLECTUAL PROPERTY AND SUSTAINABLE DEVELOPMENT*, *supra* note 84, at 97, 133 (“[T]he change in the country’s patent regime [is likely to have an impact] on the Indian generic pharmaceutical industry. The limitations imposed on the extent to which ‘me-too’ processes can be developed by the Indian industry imply that the firms would have to adopt radically different strategies under the new regime.”); Yu, *Access to Medicines*, *supra* note 67, at 388–89 (noting that the picture “may change as generic manufacturers in the BRICS countries, such as those in India, become more active in developing on-patent drugs, partly as a result of the TRIPs Agreement”). For discussions of the change in interests and configuration of the Indian generic pharmaceutical industry, *see* Dhar & Gopakumar, *supra*, at 120–22; Kenneth C. Shadlen, *Is AIDS Treatment Sustainable?*, in *GLOBAL GOVERNANCE OF HIV/AIDS*, *supra* note 16, at 29, 41–45; Dwijen Rangnekar, *Context and Ambiguity in the Making of Law: A Comment on Amending India’s Patent Act*, 10 J. WORLD INTELL. PROP. 365, 379–80 (2007).

103. Shadlen, *Is AIDS Treatment Sustainable?*, *supra* note 102, at 52 n.19; *see also* Lalitha, *supra* note 71, at 225 (“Two thirds of the drugs produced in India are exported, with destinations in North America, the European Union, CIS countries and West Africa in that order.”).

104. For discussions of the seizure of in-transit drugs, *see generally* HO, *supra* note 14, at 285–323; Frederick M. Abbott, *Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare*, 1 WIPO J. 43 (2009); Bryan Mercurio, “Seizing” Pharmaceuticals in Transit: *Analysing the WTO Dispute that Wasn’t*, 61 INT’L & COMP. L.Q. 389 (2012).

drugs.<sup>105</sup> In July 2011, India and the European Union finally reached an interim settlement.<sup>106</sup> As of this writing, both Brazil and India have yet to withdraw their complaints.

In sum, the story surrounding the lack of affordable access to HIV/AIDS treatments in less developed countries has highlighted some of the major challenges in the international patent system as well as the difficulty in making adjustments to that system. The lack of success in addressing the access-to-medicines problems through the TRIPS Agreement has also led reformers to question whether the international patent system can be further reformed, or whether reform should take place outside the TRIPS Agreement—such as through the creation of new incentive models. A case in point is the adoption of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property at the World Health Assembly in May 2008,<sup>107</sup> which has earned the support and praise of less developed country governments, nongovernmental organizations (“NGOs”), and academic commentators.<sup>108</sup>

## II. VIROTECH PATENTS

The second virostory concerns a highly contagious and panic-inducing virus: the coronavirus responsible for SARS. In spring 2003, countries in Asia and a small part of Canada were struck by a “mysterious” yet lethal disease called SARS.<sup>109</sup> Hundreds of people died, thousands more were infected, and an uncountable number of innocent bystanders were

105. See Request for Consultations by India, *European Union and a Member State—Seizure of Generic Drugs in Transit*, WT/DS408/1 (May 19, 2010); Request for Consultations by Brazil, *European Union and a Member State—Seizure of Generic Drugs in Transit*, WT/DS409/1 (May 19, 2010).

106. See *India, EU Ink Deal to End Drug Seizure for Now*, TIMES OF INDIA (July 29, 2011, 1:21 AM), [http://articles.timesofindia.indiatimes.com/2011-07-29/india-business/29828750\\_1\\_generic-drugs-consignments-of-generic-medicines-eu-parliament](http://articles.timesofindia.indiatimes.com/2011-07-29/india-business/29828750_1_generic-drugs-consignments-of-generic-medicines-eu-parliament) (reporting the European Union’s interim settlement with India).

107. Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, World Health Assembly Res. WHA61.21 (May 24, 2008) [hereinafter Global Strategy and Plan of Action].

108. See ‘T HOEN, *supra* note 63, at 92–93 (discussing the Global Strategy and praising it as “a forceful call for change”); FREDERICK M. ABBOTT & GRAHAM DUKES, GLOBAL PHARMACEUTICAL POLICY: ENSURING MEDICINES FOR TOMORROW’S WORLD 6 (2011) (“With the adoption of a Global Strategy and Plan of Action in 2008, the World Health Assembly . . . has taken a significant step toward proactively encouraging new models of innovation.”).

109. See Lawrence K. Altman & Keith Bradsher, *Rare Health Alert Is Issued by W.H.O. for Mystery Illness*, N.Y. TIMES, Mar. 16, 2003, <http://www.nytimes.com/2003/03/16/world/rare-health-alert-is-issued-by-who-for-mystery-illness.html>.

quarantined.<sup>110</sup> To prevent further spread of the disease, some governments closed schools, movie theaters, swimming pools, and other public places.<sup>111</sup> Although SARS was serious from a public health standpoint, it was even more devastating from an economic standpoint. As Georges Benjamin, the executive director of the American Public Health Association, observed:

Over 8,000 people from 29 countries became ill and about 774 died. This is in stark contrast to the approximately 3.8 million people who die annually worldwide from pneumonia, the 2.1 million who die from infectious diarrhea, and the 3.1 million who die from HIV/AIDS.

Put in this perspective, SARS was not “the big one.” It did, however, cost over US\$40 billion and served as a global wake-up call.<sup>112</sup>

Unlike the first virostory, this story covers a virus that affected both developed and less developed countries. Not only did the latter have difficulty locating responses, the former were equally clueless as to the cause of the disease, the ways to diagnose it, the treatments for it, and the precautionary measures that could be used to prevent its spread. Shortly after the outbreak, the WHO quickly put together a network of doctors and health professionals,<sup>113</sup> “collaborat[ing] around the clock to identify the

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110. See WHO, *Summary of Probable SARS Cases with Onset of Illness from 1 November 2002 to 31 July 2003* (Sept. 26, 2003), available at [http://www.who.int/csr/sars/country/table2003\\_09\\_23/en/](http://www.who.int/csr/sars/country/table2003_09_23/en/).

111. See, e.g., Clifford Krauss, *Travelers Urged to Avoid Toronto Because of SARS*, N.Y. TIMES, Apr. 24, 2003, at A1; Elisabeth Rosenthal, *SARS Outbreak Fading Away, Officials Say*, N.Y. TIMES, June 6, 2003, at A10.

112. Georges C. Benjamin, *Afterword* to BROOKES, *supra* note 27, at 235–36. Similarly, Andrew Price-Smith and Huang Yanzhong observed:

[T]he damage generated by the epidemic was not so much the result of the morbidity and mortality that SARS induced, but rather the fear and panic that the epidemic generated, both within infected areas and in uninfected populations. This fear resulted in sub-optimal economic outcomes for the entire Pacific Rim as tourism ground to halt, international trade flows were slowed, and foreign investors cautiously withdrew from the region during the crisis.

Andrew T. Price-Smith & Huang Yanzhong, *Epidemic of Fear: SARS and the Political Economy of Contagion*, in INNOVATION IN GLOBAL HEALTH GOVERNANCE 23, 24 (Andrew F. Cooper & John J. Kirton eds., 2009) (footnote omitted); see also HOW A GLOBAL EPIDEMIC WAS STOPPED, *supra* note 27, at vii (“SARS shook the world. By some standards, the first emerging and readily transmissible disease of the 21st century was not a big killer, but it caused more fear and social disruption than any other outbreak of our time.”).

113. See Moira Chan-Yeung & Christine Loh, *The New Coronavirus: In Search of the Culprit*, in AT THE EPICENTRE: HONG KONG AND THE SARS OUTBREAK 43, 45 (Christine Loh ed., 2004) [hereinafter AT THE EPICENTRE] (“[The WHO] used its electronically linked global influenza network as a model to quickly establish a similar ‘virtual’ connection among 11

cause of SARS, develop diagnostic tests, define clinical features, and investigate modes of transmission.”<sup>114</sup> As Klaus Stohr, the coordinator of the WHO Multi-centre Collaborative Network on SARS Aetiology and Diagnosis, declared, “We needed people to share data and set aside Nobel Prize interests or their desire to publish articles.”<sup>115</sup>

Notwithstanding the collaboration within this network, the SARS coronavirus sparked two different races. The first was a race to discover the genome of the coronavirus.<sup>116</sup> It involved human resources, medical technology, and scientific publications. As Moira Chan-Yeung and Christine Loh recounted, in chronological order and considerable detail:

On 2 April, the Atlanta team began to fish segments of genetic code out of the virus, posting the information they gathered on the network website so that others could use it. Meanwhile, the Michael Smith Genome Sciences Centre in Vancouver, Canada, a research facility under the British Columbia Cancer Agency [the “BCCA”], decided to try and sequence the full genome. Under Dr. Robert Holt, a group of its scientists had already been studying fast-growing diseases for a year. While their work had originally started as response to the global bio-terrorism threat, they viewed the SARS investigation as an opportunity to apply what they had learned.

The Canadian team received its first sample on 5 April. It was taken from the lung tissue of the first SARS patient infected in Toronto, a man who . . . was a “super-spreader” who had infected many people. Once his specimen arrived, nearly half of the 90 staff at the Vancouver laboratory worked on sequencing the virus.

In the early hours of 12 April, Holt’s team finished the sequencing, posting the genome map on the website later that day. On 14 April, the researchers in Atlanta completed their genome map. The two genetic blueprints were practically identical. Just days later, [a University of Hong Kong] team led by Department of Zoology professor Frederick Leung and a [Chinese University of Hong Kong] group headed by chemical pathologist Dennis Lo Yuk-ming completed the sequencing of two SARS virus strains obtained locally.

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leading laboratories around the world through a shared secure website and daily teleconference calls. The number of labs involved in the investigation was eventually increased to 13.”).

114. HOW A GLOBAL EPIDEMIC WAS STOPPED, *supra* note 27, at 54.

115. Chan-Yeung & Loh, *supra* note 113, at 46.

116. See BROOKES, *supra* note 27, at 101–19 (discussing the race to sequence the genome of the SARS coronavirus).

On 17 April, exactly a month after Stohr set up the virtual research network, the collaborators announced conclusive identification of the SARS causative agent: a new coronavirus.<sup>117</sup>

This race to sequence the SARS coronavirus was interesting, complicated, and at times error-prone. As one close observer described:

[T]he lab that is now widely acknowledged as first having identified the SARS coronavirus actually reached the finish line fifth, and even then there was a photo finish and the equivalent of a steward's inquiry. Two labs that beat it to the post got the wrong answer. The first lab to publicly identify the pathogen also got the wrong answer; and in doing so it buried the work of an entirely different lab that had got the right answer before anyone, but its researchers never published their results for fear of being punished.<sup>118</sup>

The second race concerned the patenting of isolated gene sequences associated with the SARS coronavirus.<sup>119</sup> In April 2003, the Centers for Disease Control and Prevention (the "CDC") in Atlanta, the BCCA in Vancouver, Canada, and Versitech Ltd., the commercial arm of the University of Hong Kong, battled to patent technology involving the isolated gene sequences of the SARS coronavirus.<sup>120</sup> Combimatrix, a biotechnology subsidiary of Acacia Research Corp., also filed patent applications claiming ownership of the key isolated sequences of two SARS genes that were suspected to control reproduction of the virus once it invades people.<sup>121</sup> Although patent applications were still pending at that time and no institution was therefore able to claim a monopoly on

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117. Chan-Yeung & Loh, *supra* note 113, at 50–51.

118. BROOKES, *supra* note 27, at 101; *see also* ABRAHAM, *supra* note 27, at 121 ("[The paper by Malik Peiris of the University of Hong Kong and his colleagues] published in the online edition of *Lancet* on April 8 was the first scientific paper describing the new coronavirus as the causal agent for SARS. A paper by the CDC group describing its findings was published two days later in the *New England Journal of Medicine*, as was a paper by the group of European scientists in Germany and the Netherlands.").

119. For discussions of the patenting race, see generally Matthew Rimmer, *The Race to Patent the SARS Virus: The TRIPS Agreement and Access to Essential Medicines*, 5 MELB. J. INT'L L. 335 (2004) [hereinafter Rimmer, *Race to Patent the SARS Virus*]; Peter K. Yu, *SARS and the Patent Race: What Can We Learn from the HIV/AIDS Crisis?*, FINDLAW (May 29, 2003), [http://writ.news.findlaw.com/commentary/20030529\\_yu.html](http://writ.news.findlaw.com/commentary/20030529_yu.html).

120. See Antonio Regalado, *Scientists' Hunt for SARS Cure Turns to Race for Patent Rights*, WALL ST. J., May 5, 2003, <http://online.wsj.com/article/0,,SB105209016979730900,00.html>.

121. See Paul Elias, *Race to Patent SARS Virus Renews Debate*, ASSOCIATED PRESS, May 5, 2003, <http://www.apnewsarchive.com/2003/Race-to-Patent-SARS-Virus-Renews-Debate/id-145b4e8d156cddc93e996ae52dc24ec0> [hereinafter Elias, *Race to Patent SARS*].

treatments for the disease, this patenting race sparked major concerns in the public health arena.

Under U.S. law, a patent can be granted to “anything under the sun that is made by man.”<sup>122</sup> One can claim a patent on a device, a mechanical process, a chemical compound, a computer program, a business model, or even a genetically engineered microorganism. In the beginning, the United States Patent and Trademark Office was fairly conservative in granting patents on bio-engineered organisms. That trend, however, changed in the wake of the United States Supreme Court’s 1980 landmark decision of *Diamond v. Chakrabarty*.<sup>123</sup> In this 5–4 decision, the Court upheld the patentability of a bacterium genetically engineered to “eat” crude oil.<sup>124</sup> Since *Chakrabarty*, patents have been granted on a wide variety of bio-engineered products.<sup>125</sup>

Today, naturally-occurring life forms remain ineligible for patent protection because they are not inventions “made by man.” Nevertheless, one could arguably patent any gene or life form that has been synthetically created, altered by technology, or reproduced through a novel method<sup>126</sup>—the recent *Myriad Genetics* decision notwithstanding.<sup>127</sup> With increasing progress in genetic engineering, one might wonder whether such an expansive protection of gene patents would still be desirable. As the U.K. Commission on Intellectual Property Rights (“IPR Commission”) noted, gene sequencing “is now a fully automated process, involving little creativity,” even though it once was a labor-intensive manual technique.<sup>128</sup>

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122. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952)).

123. 447 U.S. 303 (1980).

124. *See id.* at 310.

125. *See Ex Parte Allen*, 2 U.S.P.Q. 2d (BNA) 1425 (B.P.A.I. 1987), *aff’d*, 846 F.2d 77 (Fed. Cir. 1988) (extending patent protection to hydrostatically altered polyploid Pacific oysters); U.S. Patent No. 4,736,866 (filed Jun. 22, 1984) (providing patent protection for the famous “Harvard Onco-mouse”); *see also Notice by the Commissioner*, 1077 OFF. GAZ. PAT. & TRADEMARK OFFICE 24 (Apr. 21, 1987) (stating that non-naturally occurring, non-human multicellular living organisms constitute patentable subject matter).

126. *See, e.g.*, Utility Examination Guidelines, 66 Fed. Reg. 1092–93 (Jan. 5, 2001) (stipulating that human genes are patentable provided they satisfy the statutory requirements under the Patent Act).

127. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119–20 (2013) (distinguishing between naturally occurring and synthetically created DNA segments).

128. IPR COMMISSION REPORT, *supra* note 29, at 112; *see* GRAHAM DUTFIELD, INTELLECTUAL PROPERTY RIGHTS AND THE LIFE SCIENCE INDUSTRIES: PAST, PRESENT AND FUTURE 224 (2009) (“[C]onceiving the incidence of a disease (or of resistance to a disease) as being related to a specific allele and then discovering this allele to the point of localising it to part of a chromosome . . . are substantial intellectual achievements. They require a considerable amount of painstaking and time-consuming research. Sequencing the already-discovered allele, on the other hand, is relatively routine.”); Helen M. Berman & Rochelle C. Dreyfuss,



In a Congressional hearing, the former director of the National Institute of Health also testified that “many of the thousands of gene patents that have been awarded appear to reward unduly the preliminary and *frankly obvious* work of determining DNA sequence, and to diminish the value of the innovative scientific work required ultimately to determine gene function and medical utility.”<sup>129</sup>

In the past decade, commentators have widely discussed the potential chilling effect created by overprotection of patent rights. As Rebecca Eisenberg and Michael Heller pointed out, such overprotection would create a “tragedy of the anticommons,”<sup>130</sup> in which “multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use.”<sup>131</sup> Because most investors are risk-averse, they will be reluctant to invest when they are uncertain as to who owns the patent and whether liability for patent infringement will incur in the future. Thus, overprotection of patent rights may ultimately deter innovation and stifle valuable biomedical research.<sup>132</sup>

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*Reflections on the Science and Law of Structural Biology, Genomics, and Drug Development*, 53 UCLA L. REV. 871, 881 (2006) (“The labor-intensive methods of development have given way to technology-driven automated processes that make development a far easier process. Now, nucleic acid sequencing is routine and automated; protein sequences can be derived from gene sequences using computationally driven bioinformatics methods.”); see also Clarisa Long, *Patents and Cumulative Innovation*, 2 WASH. U. J.L. & POL’Y 229, 233–34 (2000) (“Th[e] explosion of genomics data and the proliferation of new information-based research approaches call into question many long-held beliefs and assumptions about the role of intellectual property rights as incentives for research discovery, incentives for technology innovation, and incentives for the diffusion of both.”).

129. *Gene Patents and Other Genomic Inventions: Hearing Before the Subcomm. on Courts and Intellectual Property of the Comm. on the Judiciary*, 106th Cong. 129 (2000) (statement of Dr. Harold Varmus, President, Memorial Sloan-Kettering Cancer Center) (emphasis added). Dr. Harold Varmus is a Nobel laureate and the former director of the National Institute of Health.

130. For discussions of the tragedy of the anti-commons in relation to biomedical research, see MICHAEL HELLER, *THE GRIDLOCK ECONOMY: HOW TOO MUCH OWNERSHIP WRECKS MARKETS, STOPS INNOVATION, AND COSTS LIVES* 49–78 (2010); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 699–700 (1998).

131. Heller & Eisenberg, *supra* note 130, at 698.

132. See Press Release, WHO, SARS Research: The Effect of Patents and Patent Applications (June 30, 2003), available at [http://www.who.int/csr/don/2003\\_06\\_30/en/index.html](http://www.who.int/csr/don/2003_06_30/en/index.html) (“In the longer term, the manner in which SARS patent rights are pursued could have a profound effect on the willingness of researchers and public health officials to collaborate during future outbreaks of new infectious diseases.”); James H.M. Simon et al., *Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: The Possible Role of Patent Pooling*, 83 BULL. WORLD HEALTH ORG. 707, 707 (2005) (pointing out that “SARS patent applications may adversely affect the development of technologies, such as vaccines, that will be covered by them”).

Even worse, obtaining patents today has to some extent become an end in itself, rather than a means to further the U.S. constitutional goal of “promot[ing] the Progress of . . . useful Arts”<sup>133</sup> or the dual TRIPS objectives of “promotion of technological innovation and . . . transfer and dissemination of technology.”<sup>134</sup> Instead of developing their own products, some patent holders seek to use patents primarily to preempt others’ research efforts and to profit from such preemption.<sup>135</sup> They apply for patents not because they want to develop products, but because they want to prevent business rivals from engaging in competitive research. The so-called “patent trolls,” “non-practicing entities,” or “patent assertion entities” also apply for patents so that they can obtain licensing fees or be “bought out” by companies who need to develop the patented products.<sup>136</sup>

Given these developments, it is no surprise that both the CDC and the BCCA were highly concerned about the lack of availability of essential information needed to protect the public interest in their battle against SARS. In the end, these publicly-funded agencies filed applications for patents involving the SARS coronavirus and justified those applications as a protective tool to ensure that the scientific and medical communities maintain open access to the virus for research and other purposes. As a BCCA representative noted, “Patents are in and of themselves not a good or bad thing. The thing that makes a patent leave a nasty taste . . . is when they seem to cut people out from access they should have.”<sup>137</sup>

The CDC went even further to note their skepticism about the intentions of its Hong Kong rival. When asked about Versitech’s patent application, the director of the CDC’s technology transfer office responded, “To the

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133. U.S. CONST. art. I, § 8, cl. 8.

134. TRIPS Agreement art. 7; see also Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement*, 46 HOUS. L. REV. 979, 1035–37 (2009) [hereinafter Yu, *Objectives and Principles*] (providing an in-depth discussion of the objectives and principles of the TRIPS Agreement).

135. See Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75, 84–91 (1994) (discussing the bargaining breakdown involving blocking patents); see also Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, in 1 INNOVATION POLICY AND THE ECONOMY 119, 120 (Adam B. Jaffe et al. eds., 2001) (describing the patent thicket as “a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology”).

136. See, e.g., Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991, 2008–10 (2007) (discussing patent trolls); Nicholas Varchaver, *The Patent King*, FORTUNE, May 14, 2001, at 202 (recounting the tactics deployed by Jerome Lemelson, dubbed the “Patent King”).

137. *Government, Firms Race to Patent SARS Virus*, WASH. TIMES, May 8, 2003, <http://www.washingtontimes.com/news/2003/may/8/20030508-025509-5928r/>.

extent there might be a competition, I don't think our goals are the same."<sup>138</sup> Understandably, the CDC mistrusted the motives behind its competitor's patent application, especially when that competitor was located in a foreign country. To many countries, however, it is equally troubling to think of the scenario when the CDC or the BCCA is awarded the SARS patent.

Consider the CDC for example. With the economic sanctions the United States has imposed on countries such as Cuba, Iran, and North Korea, one has to wonder whether research institutions from these sanctioned countries would receive fair and equal treatment to obtain a license to use the patented technology.<sup>139</sup> Even if the agency were willing to donate all the royalties to SARS research, there remained politically sensitive questions as to which research institutions would be eligible for the donated funds, whether conditions would be put on research funded by this donation, and whether research institutions in other countries would be able to benefit equally from the royalty pool. After all, it is no news that governments act in their own interests.

Moreover, when the CDC publicly announced its successful identification of a new coronavirus as the likely causative agent for SARS, it mysteriously did not mention any contribution made by the team from the University of Hong Kong, led by microbiologist Malik Peiris. As David Quammen recalled:

The CDC announcement [that its scientists had identified a new coronavirus as the likely cause of SARS] didn't mention that Malik Peiris and his team had found the same virus and confirmed its connection with SARS three days before. That act of claiming priority by the CDC, unnoticeable to the world at large, probably put the Hong Kong University scientists on edge against their competitors in Atlanta and elsewhere . . . .<sup>140</sup>

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138. Peg Brickley, *Preemptive SARS Patents*, SCIENTIST MAG., May 9, 2003, <http://www.the-scientist.com/?articles.view/articleNo/22173/title/Preemptive-SARS-patents/>.

139. *But see* Comm. on Econ., Soc. & Cultural Rights, *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights)*, ¶ 41, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000) [hereinafter *General Comment No. 14*] ("States parties should refrain at all times from imposing embargoes or similar measures restricting the supply of another State with adequate medicines and medical equipment. Restrictions on such goods should never be used as an instrument of political and economic pressure.").

140. DAVID QUAMMEN, SPILLOVER: ANIMAL INFECTIONS AND THE NEXT HUMAN PANDEMIC 190 (2012); *see also* ABRAHAM, *supra* note 27, at 121 ("Just so you are clear, the virus was first found in Hong Kong, first identified in Hong Kong. And then it was identified in the CDC. And now it has been identified by all the other laboratories." (quoting David Heymann, the WHO Executive Director, in a press conference in Geneva)).

Indeed, Peiris claimed that “[w]hen it became clear others were seeking patents, the Hong Kong team then sought one,” not the other way around.<sup>141</sup> In an interview with the National Public Radio, Yu Hailson, Versitech’s deputy managing director, also explained: “If we didn’t patent, for example, if there is a third party [and] they file a similar patent, and then eventually if we have to pay a license fee to do the research and development work on that subject matter, I don’t think it is reasonable and logical.”<sup>142</sup> According to Yu, if the SARS-related patent is eventually granted, Versitech “can license it for \$1 or one penny . . . to grant the right for them to do the research.”<sup>143</sup>

Regardless of how the CDC, the BCCA, and Versitech would ultimately handle their patents if they were granted, their eagerness to patent the virus to promote the public interest has raised intriguing questions about the need for “defensive patenting.”<sup>144</sup> In this case, the agencies were not patenting to profit from a monopoly over technology involving the claimed isolated sequences. Instead, by patenting the technology and subsequently introducing free licenses, these agencies sought to prevent others from abusing such a monopoly.

The patenting approach is also interesting because the natural response for those opposing gene patents would be to destroy novelty by publishing the discovery in scientific journals, such as *Lancet*, *Nature*, or *Science*,<sup>145</sup> as

141. Elias, *Race to Patent SARS*, *supra* note 121.

142. *Research Lab Tries to Patent Virus Causing SARS*, NAT’L PUB. RADIO (May 9, 2003), <http://www.npr.org/templates/story/story.php?storyId=1258427>, cited in Rimmer, *Race to Patent the SARS Virus*, *supra* note 119, at 347–48.

143. *Id.*

144. As now Judge Kimberly Moore explained:

Defensive patenting often exists in a crowded art to provide the party with a repertoire of patents to use defensively as counterclaim weapons. These patents are used to strengthen a firm’s negotiating position with competitors (e.g., as in cross-licensing). These patents may never be asserted affirmatively, but are maintained for defensive purposes when the patentee is threatened by competitors in a related field. It may be that foreign inventors acquire U.S. patents for these defensive and signaling reasons to gain bargaining power in negotiations with competitors who threaten litigation.

Kimberly A. Moore, *Xenophobia in American Courts*, 97 NW. U. L. REV. 1497, 1533 (2003); see also Rimmer, *Race to Patent the SARS Virus*, *supra* note 119, at 339 (“Michael Stratton and Cancer Research UK successfully sought a defensive patent in the European Patent Office in respect of research associated with the breast cancer-related gene, BRCA2. Such a measure was designed to prevent rival Myriad Genetics from engaging in the exclusive licensing of genetic tests for BRCA2.” (footnote omitted)).

145. See John Sulston, *Intellectual Property and the Human Genome*, in GLOBAL INTELLECTUAL PROPERTY RIGHTS: KNOWLEDGE, ACCESS AND DEVELOPMENT 61, 66 (Peter Drahos & Ruth Mayne eds., 2002) (“Not only was the released [gene] sequence immediately

opposed to engaging in a patenting race. Nevertheless, as Richard Gold pointed out:

[T]here are good reasons why the CDC and the BCCA actually prefer the patent option. First, this option provides them with more leverage in dealing with the University of Hong Kong's Versitech Ltd, which has also applied for a patent. Second, and more importantly, publishing is not enough for the two agencies to prevent others from patenting the SARS genome given their goal of preserving the public domain.<sup>146</sup>

In fact, even though the sequences identified by the Human Genome Project have become public information, firms remain very eager to apply for patents involving the identified sequences. Thus, publication alone may not provide the sufficient defense sought by the CDC and the BCCA.

After more than 8000 reported cases in twenty-nine countries, SARS finally came under control.<sup>147</sup> Although SARS no longer wreaks havoc in the global public health system, it remains intriguing to explore what has now happened to the SARS-related patents. As researchers from the Erasmus Medical Center surmised:

[I]t is likely that patent rights incorporating the SARS genomic sequence will be fragmented across several groups. Sorting out these rights will be complex and may require intervention of the

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useful for research but also it became prior art and the process of sequencing became more obvious: both of these attributes would undermine attempts at patenting sequence in the future.”); see also *id.* at 65 (discussing Celera's publication of the draft sequences in *Science* in February 2001).

146. E. Richard Gold, *SARS Genome Patent: Symptom or Disease?*, 361 LANCET 2002, 2002 (2003). In response to Professor Gold's charge against Versitech, Tsui Lap-Chee, the vice-chancellor of the University of Hong Kong (HKU) and a leading authority in genetics, wrote:

I wish to make clear that HKU is a research-led institution, committed to the public cause of higher education and benefiting society. Versitech is a technology transfer company, established in accordance with good practices of international universities to handle HKU's intellectual properties. Neither HKU nor Versitech are profit-seeking organisations, and they both hold the same view as CDC and BCCA—namely, to serve the public.

HKU is committed to sharing its research results with society; locally, regionally, and internationally. We will continue to build up our research strength, but we cannot hope to share the benefits of our newly found knowledge if we do not properly manage our intellectual property rights.

Tsui Lap-Chee, *SARS Genome Patent: To Manage and to Share*, 362 LANCET 405, 405 (2003). In the interest of full disclosure, the Author has repeatedly served as a visiting professor in the Faculty of Law at the University of Hong Kong.

147. See HOW A GLOBAL EPIDEMIC WAS STOPPED, *supra* note 27, at 49 (providing the WHO's official figure at “8,098 cases, with 774 deaths, . . . in 29 countries and areas”).

law court. . . . [For firms considering whether to develop a SARS vaccine], uncertainty over patent rights makes this decision even more difficult, because it is neither possible to determine the future cost of licensing the patent rights, nor whether all necessary patents will be available for licensing. . . . The incentive for vaccine manufacturers is therefore to delay the decision to invest.<sup>148</sup>

To prevent the SARS-related patents from creating a patent thicket, the patent applicants eventually agreed to collaborate with each other through the establishment of a patent pool.<sup>149</sup> The setting up of this pool is not new. Such an arrangement has been used as early as the mid-nineteenth century; it has since covered technologies ranging from sewing machines to aircrafts to information and communication technology.<sup>150</sup> Nevertheless, the SARS patent pool is somewhat different from many existing patent pools. As Dianne Nicol and Jane Nielsen noted:

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148. Simon et al., *supra* note 132, at 708, *quoted in* HELLER, *supra* note 130, at 54; *see also* Rimmer, *Race to Patent the SARS Virus*, *supra* note 119, at 374 (noting the concerns in 2004 that “patent rights are impeding efforts to prevent an outbreak of bird flu—avian influenza”); Birgit Verbeure, *Patent Polling for Gene-based Diagnostic Testing*, in GENE PATENTS AND COLLABORATIVE LICENSING MODELS: PATENT POOLS, CLEARINGHOUSES, OPEN SOURCE MODELS AND LIABILITY REGIMES 3, 18 (Geertrui Van Overwalle ed., 2009) (“The WHO set up a SARS consultation group which proposed ‘that a strategy be developed, in consultation with stakeholders, to address potential SARS corona virus related [intellectual property] issues and thus enhance development of intervention approaches.’”).

149. “A patent pool has been commonly defined as an agreement between two or more patent owners to license one or more of their patents to one another or as a package to third parties who are willing to pay the royalties associated, either directly by patentees to licensees or, indirectly, through a new entity specifically set up for the pool administration.” Geertrui Van Overwalle, *Of Thickets, Blocks and Gaps: Designing Tools to Resolve Obstacles in the Gene Patents Landscape*, in GENE PATENTS AND COLLABORATIVE LICENSING MODELS, *supra* note 148, at 383, 405.

150. As one commentator observed:

One of the first patent pools was formed in 1856, by sewing machine manufacturers Grover, Baker, Singer, Wheeler and Wilson, all accusing the others of patent infringement. They met in Albany, New York to pursue their suits. Orlando B. Potter, a lawyer and president of the Grover and Baker Company, proposed that, rather than sue their profits out of existence, they pool their patents. In 1917, an aircraft pool was privately formed encompassing almost all aircraft manufacturers, which was crucial to the US government entering World War I. In the late 1990s several patent pools were formed in the ICT branch starting with the MPEG-2 pool in 1997 for inventions relating to the MPEG-2 standard with others to follow.

Verbeure, *supra* note 148, at 3–4; *see also* Adam Mossoff, *The Rise and Fall of the First American Patent Thicket: The Sewing Machine War of the 1850s*, 53 ARIZ. L. REV. 165, 166–70 (2011) (discussing the patent pool involving sewing machines).

First, the patent owners are mostly non-profit organizations. Other patent pools tend to be creatures of the commercial sector, or include at least some commercial partners. Second, the technology is very much at the early discovery phase of the innovation cycle rather than the downstream delivery phase. Third, the patents have not yet been issued and so the scope of their claims is not yet known. Finally, once issued, the patents may be competing rather than complementary, given that each of the participants was involved in sequencing the virus.<sup>151</sup>

The SARS patent pool can be beneficial for several reasons.<sup>152</sup> First, patent pools provide an efficient and effective solution when patent rights are highly fragmented.<sup>153</sup> As far as the SARS-related patents are concerned,<sup>154</sup> the uncertainty over who owns what “may remain for years,

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151. Dianne Nicol & Jane Nielsen, *Opening the Dam: Patent Pools, Innovation and Access to Essential Medicines*, in INCENTIVES FOR GLOBAL PUBLIC HEALTH, *supra* note 63, at 235, 250.

152. Nevertheless, patent pools can have some major drawbacks, such as “the shielding of invalid patents” and “the risk of inequitable remunerations.” Van Overwalle, *supra* note 149, at 407. Indeed, these pools “could be both anti-competitive, particularly if they encourage collusion and shield weak patents, and anti-innovative (or innovation-neutral), particularly if they don’t include all necessary patents or are poorly managed and inadequately resourced.” Nicol & Nielsen, *supra* note 151, at 237. In addition, patent pools could “lead to increased complexity and transaction costs,” as “[t]hey are expensive to establish and administer, and this tends to lessen the incentive to voluntarily enter into pooling arrangements.” *Id.* at 253 (footnote omitted). They “may also disadvantage licensees by requiring them to license all the patents in a package, even those that are not required by a particular licensee.” *Id.* at 257. Finally, patent pools do not work well for diverse parties. As Dianne Nicol and Jane Nielsen explained: “[T]he interests of pool members are frequently non-aligned. This non-alignment issue is likely to be most pronounced for pools that attempt to span the whole innovation cycle. Holders of upstream research tool patents have very different motivations from holders of downstream formulation patents, for example.” *Id.* at 253–54.

153. As researchers from the Erasmus Medical Center observed:

Given that groups from several institutions, including the Bernhardt-Nocht Institut (BNI), the [BCCA, the CDC], Erasmus Medical Centre (EMC) and Hong Kong University (HKU), were simultaneously involved in the sequencing of [the SARS coronavirus], it is likely that patent rights incorporating the SARS genomic sequence will be fragmented across several different groups. Sorting out these rights will be complex and may require the intervention of law courts.

Simon et al., *supra* note 132, at 707–08; *see also* ‘T HOEN, *supra* note 63, at 90 (“Potential benefits of pooling include: a) reduced licensing transaction costs through ‘one stop’ licensing rather than multiple agreements; b) elimination of blocking patents; c) management of multiple owners and stacking of royalties . . .”).

154. *See, e.g.*, Coronavirus Isolated from Humans, U.S. Patent No. 7,220,852 (filed Apr. 12, 2004) (issued May 22, 2007); Human Virus Causing Severe Acute Respiratory Syndrome (SARS) and Uses Thereof, U.S. Patent No. 7,375,202 (filed Mar. 24, 2004) (issued May 20, 2008); SARS Virus Nucleotide and Amino Acid Sequences and Uses Thereof, U.S. Patent Application No. 20,070,258,999 (filed Apr. 28, 2004). These patents were cited in Ed Levy et

delaying development that could help us to be prepared efficiently for any next outbreak.”<sup>155</sup> Second, “[p]atent pools may . . . offer an interesting instrument for government policy, in the sense that it is better to encourage companies to establish patent pools rather than for example to force them into a compulsory licensing scheme.”<sup>156</sup> Third, as Frederick Abbott and Graham Dukes observed: “Patent pools are sufficiently common as to have become subject to a fairly sophisticated level of regulation, for example, in the European Commission guidelines on technology transfer. Many of the issues surrounding the negotiation and implementation of patent pools already are anticipated by competition authorities.”<sup>157</sup> Fourth, as the WHO Commission on Intellectual Property Rights, Innovation and Public Health declared: “Patent pools of upstream technologies may be useful in some circumstances to promote innovation relevant to developing countries.”<sup>158</sup> Likewise, the Antitrust Guidelines for the Licensing of Intellectual Property, issued jointly by the U.S. Department of Justice and the Federal Trade Commission, suggested that patent pools “may provide procompetitive benefits by integrating complementary technologies, reducing transaction costs, clearing blocking positions, and avoiding costly infringement litigation.”<sup>159</sup> Finally, patent pools provide additional benefits

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al., *Patent Pools and Genomics: Navigating a Course to Open Science?*, 16 B.U. J. SCI. & TECH. L. 75, 89 n.75 (2010).

155. Carmen E. Correa, *Case 2. The SARS Case: IP Fragmentation and Patent Pools*, in GENE PATENTS AND COLLABORATIVE LICENSING MODELS, *supra* note 148, at 42, 45. As one commentator explained:

The uncertainty over patent rights represents a challenge to product development because companies willing to develop any SARS-related product need to deal with several [intellectual property] applicants holding primary patents, but they do not know from which they will get a license, or if they will require to license from all such patent holders. This uncertainty adds to the complexity to assemble a license, which translates in additional costs and time to the product development. Together with the challenge to decide whether to invest at such a high cost when they are not even sure whether a market will develop for their products—no significant outbreaks since 2003—setting up a patent pool is a real challenge.

*Id.*; see also Jorge A. Goldstein, *Critical Analysis of Patent Pools*, in GENE PATENTS AND COLLABORATIVE LICENSING MODELS, *supra* note 148, at 50, 51 (“[T]he SARS example shows that the uncertainty of who would own what patent rights at the end of the day provided an additional impetus to think about and attempt to create a patent pool.”).

156. Verbeure, *supra* note 148, at 9.

157. ABBOTT & DUKES, *supra* note 108, at 39.

158. WHO, COMM’N ON INTELLECTUAL PROP. RIGHTS, INNOVATION & PUB. HEALTH, PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS 53 (2006) [hereinafter CIPRIH REPORT].

159. U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 5.5 (1995), available at <http://www.usdoj.gov/atr/public/guidelines/0558.pdf>; see also Nicol & Nielsen, *supra* note 151,



that could be especially attractive to less developed countries. For example, Ellen 't Hoen pointed out that these pools have the potential to both “encompass non-patent technology and know-how” and “facilitate technology transfer and a sustainable scaling-up of capacity and access in the developing world.”<sup>160</sup>

Given the benefits of patent pools, it is no surprise that such an arrangement has also been recently used to address access-to-medicines problems in the context of HIV/AIDS treatments, the focus of the first virostory. Established in 2010 as a spinoff from UNITAID, a global health initiative financed by levies on plane tickets, the Medicines Patent Pool aims to “increase access to quality, appropriate, affordable medicines for people living with HIV in developing countries.”<sup>161</sup> In July 2011, the Pool entered into a license agreement with Gilead Sciences to “allow for the production of key HIV medicines at lower cost and in an easier-to-use formulation, making them more accessible to developing countries.”<sup>162</sup>

To a large extent, the establishment of the Medicines Patent Pool reminds us of the need for greater cooperation to address international disputes that could jeopardize valuable scientific and medical research. One might still recall the dispute between France and the United States over who discovered the AIDS virus and who owned the commercial rights in a blood test that emerged from research leading to the discovery.<sup>163</sup> Fortunately, a

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at 237 (“Provided that a patent pool includes all relevant patents, it can create a platform for freedom to operate . . . within the patent landscape.”).

160. 'T HOEN, *supra* note 63, at 90.

161. *About the MPP*, MEDICINES PATENT POOL, <http://www.medicinespatentpool.org/about/> (last visited Nov. 9, 2013). This pool aims to “facilitate[] the production of low-cost versions of existing medicines as well as the development of needed new formulations, such as ‘fixed-dose combinations’—one pill comprised of several medicines that increase treatment adherence—and formulations suitable for children.” *Id.*

162. William New, *Medicines Patent Pool Boosts HIV Drug Prospects with First Licence*, INTELL. PROP. WATCH (July 12, 2011, 9:04 AM), <http://www.ip-watch.org/2011/07/12/medicines-patent-pool-boosts-hiv-drug-prospects-with-first-licence/>.

163. As Thomas Pogge, Matthew Rimmer, and Kim Rubenstein recounted:

In May 1983, Luc Montagnier, Françoise Barré-Sinoussi and other French scientists from the Institut Pasteur in Paris published a paper in *Science*, detailing the discovery of a virus called lymphadenopathy (‘LAV’). A scientific rival, Robert Gallo of the National Cancer Institute, identified the AIDS virus and published his findings in the May 1984 issue of *Science*. In May 1985, the United States Patent and Trademark Office awarded the American patent of the AIDS blood test to Gallo and the Department of Health and Services. In December 1985, the Institut Pasteur sued the Department of Health and Human Services, contending that the French were the first to identify the AIDS virus and to invest the antibody test, and that the American test was dependent upon the French research.

1987 agreement between President Ronald Reagan and French Prime Minister Jacques Chirac split the patent rights and donated the royalties to AIDS research.<sup>164</sup> Were it not for this ground-breaking agreement, companies that produce diagnostic products might still remain confused about the commercial rights relating to the products, not to mention that they would be reluctant to invest in developing tests that help diagnose HIV/AIDS in the first place.

In sum, the race to patent the isolated gene sequences of the SARS coronavirus has raised important questions in both the intellectual property and public health arenas. As of this writing, SARS no longer poses a recurring threat to the international community, thus undermining the market value of SARS vaccines and SARS-related patents.<sup>165</sup> Nevertheless, this story is different from the earlier one concerning HIV/AIDS. Instead of calling for adjustments to the existing international patent system, countries in this story took proactive efforts toward solving the problems within the system. From engaging in a patenting race to the deployment of defensive patenting to the development of a patent pool, the SARS story has shown

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Thomas Pogge et al., *Access to Essential Medicines: Public Health and International Law*, in INCENTIVES FOR GLOBAL PUBLIC HEALTH, *supra* note 63, at 1–2.

164. As Pogge, Rimmer, and Rubenstein continued:

In March 1987, an agreement was brokered by President Ronald Reagan and French Prime Minister Jacques Chirac, which resulted in the Department of Health and Human Services and the Institut Pasteur sharing the patent rights to the blood test for AIDS. In 1992, the Federal Office of Research Integrity found that Gallo had committed scientific misconduct, by falsely reporting facts in his 1984 scientific paper. A subsequent investigation by the National Institutes of Health, the US Congress and the US Attorney-General cleared Gallo of any wrongdoing.

In 1994, the US Government and the French Government renegotiated their agreement regarding the AIDS blood test patent, in order to make the distribution of royalties more equitable. Under the agreement, the US and French research institutions would keep 20 per cent of royalties made from testing kits that each team has developed from its own laboratories. The remaining 80 percent would be pooled. A quarter of the pool was allocated to the World AIDS Foundation. Under the agreement, the French received two thirds of the remainder and the Americans one third.

*Id.* at 2. For discussions of this agreement, see also Deborah M. Barnes, *AIDS Patent Dispute Settled*, 236 SCI. 17, 17 (1987); Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 226–29 (1987); Howard L. Singer, *Institut Pasteur v. United States: The AIDS Patent Dispute, the Contract Disputes Act and the International Exchange of Scientific Data*, 15 AM. J.L. & MED. 439, 439–41 (1989).

165. See Nicol & Nielsen, *supra* note 151, at 250 (“While the SARS proposal might have provided a useful model for more broadly based discovery phase patent pooling, further development of the pool has been stalled given that there is no pressing need to develop a SARS vaccine at the present time.”).

how countries can take advantage of the international patent system to promote self-interests.

### III. VIROPIRACY AND VIRAL SOVEREIGNTY

The third virostory concerns a lesser known virus: the H5N1 strain of the avian influenza A. Avian influenza, or what is generally known as the “bird flu,” is dangerous because it “is more contagious and virulent than SARS and can be spread by asymptomatic carriers.”<sup>166</sup> Nonetheless, avian influenza is not commonly found in developed countries, as increased urbanization, a growing emphasis on service industries, and the practice of commercial farming have greatly reduced human contact with poultry and farm animals. In fact, many policymakers and the mainstream media in the United States did not pay much attention to the virus until the arrival of the H1N1 strain of Influenza A, the so-called “swine flu virus.”<sup>167</sup> Before the arrival of that strain, many expected H5N1, not H1N1, to be responsible for the next pandemic.<sup>168</sup>

When H1N1 crossed over from pigs to humans and began to spread,<sup>169</sup> the WHO, national and state governments, and public institutions (including schools and universities) went into high alert, fearing that H1N1 would wreak havoc the same way SARS did.<sup>170</sup> Compared with the response to SARS, the response to H1N1 was much quicker and more effective.

166. John J. Kirton & Andrew F. Cooper, *Innovation in Global Health Governance*, in *INNOVATION IN GLOBAL HEALTH GOVERNANCE*, *supra* note 112, at 309, 311.

167. See David Brown, *New Strain of Swine Flu Investigated*, WASH. POST, Apr. 22, 2009, at A6.

168. As Ian Scoones observed:

Since the outbreak of avian influenza in Hong Kong, and the subsequent death of six people, the world has been expecting the next pandemic to be the H5N1 virus, coming from birds and with an origin in Asia. Instead, a different virus struck—H1N1. It was originally derived from pigs, but also mixed with human and avian genetic material; it came from the Americas and quickly spread across the world.

Ian Scoones, *Preface to AVIAN INFLUENZA*, *supra* note 28, at xi, xi.

169. As David Quammen explained:

Pigs offer conditions intermediate between what a flu virus finds in people and what it finds in birds; therefore pigs get infected with both human subtypes and bird subtypes. When an individual pig is infected simultaneously with two viruses—one adapted to humans, one adapted to birds—the opportunity exists for reassortment between those two.

QUAMMEN, *supra* note 140, at 507.

170. See David Brown, *U.S. Steps up Alert as More Swine Flu Is Found*, WASH. POST, Apr. 27, 2009, at A1 (reporting that the U.S. government declared H1N1 as a “public health emergency”).

Although we will never know whether H1N1 could produce as much devastation as SARS had these responses not been taken, it is worth noting that the threats created by SARS and H1N1 remain far from over. Only recently, reports have emerged about the outbreak of a new SARS-like coronavirus in the Middle East and the United Kingdom, which was responsible for a disease now termed the Middle East Respiratory Syndrome (“MERS”).<sup>171</sup> The outbreak of the H7N9 strain of the avian influenza virus in China has also caught the attention of both the WHO and the media.<sup>172</sup> Recent scientific evidence suggested that this strain has the capacity to transmit among humans.<sup>173</sup>

This Part focuses primarily on H5N1, the bird flu virus, for two reasons. First, the virus is found more frequently in less developed countries than developed countries. Birds and poultry stricken with the virus, for example, have been found in Hong Kong, Indonesia, mainland China, South Korea, and Thailand.<sup>174</sup> Second, the H5N1 story helps bring out an issue that has not yet arisen in the first two virostories. Although less developed countries have expressed grave concern about the lack of protection for traditional knowledge, traditional cultural expressions, and genetic resources since the formation of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore in September 2000,<sup>175</sup> these issues did not come up in either the first or second story. This concern, however, has become a major part of the H5N1 story.

On February 16, 2007, Siti Fadilah Supari, the Minister of Health of Indonesia at the time, informed senior WHO officials that Indonesia would no longer send virological materials to the WHO Global Influenza Surveillance Network (“GISN”) unless a new global mechanism for virus sharing with better terms for less developed countries was to be developed.<sup>176</sup> As Supari declared:

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171. See, e.g., Maria Cheng, *SARS-like Virus Detected in the Middle East*, WASH. POST, Sept. 26, 2012, at A2.

172. See Lena H. Sun, *Bird Flu Death Toll Rises to Six in China*, WASH. POST, Apr. 4, 2013, at A3; Press Release, WHO, Human Infection with Influenza A(H7N9) Virus in China (Apr. 1, 2013), available at [http://www.who.int/csr/don/2013\\_04\\_01/en/index.html](http://www.who.int/csr/don/2013_04_01/en/index.html).

173. *Evidence New Bird Flu Spread Between Humans*, S. CHINA MORNING POST, Aug. 8, 2013, at 3.

174. See Sonny Shiu-Hing Lo, *SARS and Avian Influenza in China and Canada: The Politics of Controlling Infectious Disease*, in INNOVATION IN GLOBAL HEALTH GOVERNANCE, *supra* note 112, at 83, 83.

175. For the Author’s earlier discussion of these issues, see generally Peter K. Yu, *Cultural Relics, Intellectual Property, and Intangible Heritage*, 81 TEMP. L. REV. 433 (2008) [hereinafter Yu, *Cultural Relics*].

176. See RI “Will Not Share” Flu Samples, JAKARTA POST, Feb. 17, 2007, <http://www.thejakartapost.com/news/2007/02/17/ri-039will-not-share039-flu-samples.html>.

Indonesia will insist on a material transfer agreement before sending the Indonesian strain of bird flu virus to foreign laboratories to prevent them from being used for commercial purposes . . . . We agree to send the virus to the WHO with new conditions or mechanisms approved by both parties as well as by other developing countries. Until then, we won't share the samples.<sup>177</sup>

The predecessor of the WHO Global Influenza Surveillance and Response System ("GISRS"), GISA is a network comprising WHO collaborating centers, national influenza centers, and regulatory and reference laboratories.<sup>178</sup> In the past, countries submitted virus samples to the WHO voluntarily and free-of-charge for the purposes of surveillance, risk assessment, warning, and vaccine development.<sup>179</sup> This time, however, Indonesia withheld the samples and struck a deal with "Baxter Healthcare SA to develop human vaccines with the Indonesian strain."<sup>180</sup>

Indonesia's decision to protect "viral sovereignty"<sup>181</sup> was highly problematic from a public health standpoint. It "sent a shock wave through the international health, diplomatic and academic communities."<sup>182</sup> As the late Richard Holbrooke and Laurie Garrett recounted, "The vast majority of repeated avian flu outbreaks the past four years, in both humans and

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177. *Id.*

178. Information about the GISRS is available at [http://www.who.int/influenza/gisrs\\_laboratory/en/](http://www.who.int/influenza/gisrs_laboratory/en/). GISRS was established in November 2011, following the adoption of the Pandemic Influenza Preparedness Framework at the 64th World Health Assembly in May 2011. The network now comprises six WHO collaborating centers in Atlanta, Beijing, London, Melbourne, Memphis, and Tokyo, more than a hundred national influenza centers, and additional essential regulatory and reference laboratories.

179. As David Fidler and Lawrence Gostin explained:

Analyzing pathogen samples allows public health officials to understand what disease-causing organisms are circulating within populations. Such samples are very important for conducting surveillance on changes in pathogen strains, such as the development of drug-resistant strains. Surveillance information allows public health to update diagnostic reagents and to develop interventions (e.g., vaccines, antibiotics) to address the characteristics of the viral or bacterial strain in question.

DAVID FIDLER & LAWRENCE GOSTIN, BIOSECURITY IN THE GLOBAL AGE: BIOLOGICAL WEAPONS, PUBLIC HEALTH, AND THE RULE OF LAW 170–71 (2007).

180. *RI "Will Not Share" Flu Samples*, *supra* note 176.

181. Supari herself did not use the term "viral sovereignty." Policymakers and commentators, however, have picked up that term. *See, e.g.*, Kenan Mullis, Note, *Playing Chicken with Bird Flu: "Viral Sovereignty," the Right to Exploit Natural Genetic Resources, and the Potential Human Rights Ramifications*, 24 AM. U. INT'L L. REV. 943 (2009); Richard Holbrooke & Laurie Garrett, 'Sovereignty' that Risks Global Health, WASH. POST, Aug. 10, 2008, at B7.

182. Paul Forster, *On a Wing and a Prayer: Avian Influenza in Indonesia*, in AVIAN INFLUENZA, *supra* note 28, at 131, 158.

poultry, have occurred in Indonesia. At least 53 types of H5N1 bird flu viruses have appeared in chickens and people there . . . .”<sup>183</sup> Nevertheless, Indonesia’s controversial effort earned the sympathy of the editor of *Lancet*, one of the world’s oldest and most respected medical journals. Describing Indonesia’s attempt to secure an affordable vaccine supply for its population as “understandable,” a journal editorial lamented:

To protect the global population, 6.2 billion doses of pandemic vaccine will be needed, but under current manufacturing capacity the world can only produce 500 million doses. And, in a pandemic, it is industrialised countries that will have access to available vaccines, whereas developing countries—where a pandemic is likely to emerge—will be left wanting. In November, 2004, a WHO consultation reached the depressing conclusion that most developing countries would have no access to vaccine during the first wave of a pandemic and possibly throughout its duration.<sup>184</sup>

Indonesia’s position can be attributed to five factors. First, and most importantly, Indonesia was concerned that the WHO would share the viruses with brand name pharmaceutical companies without their authorization. As People’s Health Movement, Medact, and Global Equity Gauge Alliance recounted in their *Alternative World Health Report*:

The Indonesian government discovered that avian flu viral material that it had voluntarily submitted to the GISN ended up in the hands of pharmaceuticals companies for vaccine development, without its permission. This was contrary to WHO guidelines, which state that any further distribution of viruses beyond the WHO reference laboratories must require the permission of the originating country.<sup>185</sup>

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183. Holbrooke & Garrett, *supra* note 181.

184. Editorial, *Global Solidarity Needed in Preparing for Pandemic Influenza*, 369 LANCET 532, 532 (2007) [hereinafter *Global Solidarity Needed*].

185. PEOPLE’S HEALTH MOVEMENT ET AL., GLOBAL HEALTH WATCH 2: AN ALTERNATIVE WORLD HEALTH REPORT 232–33 (2008) [hereinafter ALTERNATIVE WORLD HEALTH REPORT] (citation and footnote omitted); accord Charles Lawson & Barbara Ann Hocking, *Accessing and Benefit Sharing Avian Influenza Viruses Through the World Health Organization: A CBD and TRIPS Compromise Thanks to Indonesia’s Sovereignty Claim?*, in INCENTIVES FOR GLOBAL PUBLIC HEALTH, *supra* note 63, at 284, 298 (noting “Indonesia’s concern that an Indonesian provided H5N1 virus sample provided to the WHO’s Global Influenza Surveillance Network . . . was given to an Australian vaccine manufacturer that intended to patent (in some respect) the vaccine that Indonesia would then need to purchase”); see also *id.* at 309 (viewing “Indonesia’s recourse to [the benefit-sharing and informed consent obligations] . . . as a direct result of the GISN apparent breach of trust”).

Indeed, it is not irrational for Indonesia—or, for that matter, other less developed countries—to fear that brand name pharmaceutical companies would exploit the genetic sequence data from the submitted viral samples, to the point that the supplied samples would return to haunt the country in the form of high prices and inaccessible vaccines and antivirals.<sup>186</sup> Because both developed and less developed countries have an equally strong demand for vaccines, those vaccines are likely to be priced according to the economic ability of developed countries, not their less developed counterparts.

Second, even if less developed countries could afford the vaccines—which is very unlikely—they might be unable to successfully compete with developed countries for the limited supply of vaccines. The *Lancet* editorial already stated that the world could only produce 500 million doses of pandemic vaccine even though 6.2 billion doses would be needed.<sup>187</sup> Because “drug companies can produce only a limited amount of vaccines in a given year, many developed countries have [already] made advance purchase orders for vaccines, limiting even further the prospects of countries like Indonesia benefiting from vaccine development.”<sup>188</sup>

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186. See David P. Fidler, *Negotiating Equitable Access to Influenza Vaccines: Global Health Diplomacy and the Controversies Surrounding Avian Influenza H5N1 and Pandemic Influenza H1N1*, 7 PLOS MED. e1000247 (2010) [hereinafter Fidler, *Negotiating Equitable Access*] (noting “developing-country concerns that their populations would not have access to H5N1 vaccines”); *Indonesia Stops Announcing Bird Flu Deaths on Case-by-Case Basis*, ASSOCIATED PRESS, June 5 2008, <http://www.thejakartapost.com/news/2008/06/05/indonesia-stops-announcing-bird-flu-deaths-casebycase-basis.html> [hereinafter *Indonesia Stops Announcing Bird Flu Deaths*] (“[Indonesia Minister of Health Siti Fadilah Supari] worried that pharmaceutical companies would use her country’s viruses to make vaccines that [a]re ultimately unaffordable for developing countries.”).

187. See *Global Solidarity Needed*, *supra* note 184, at 532.

188. ALTERNATIVE WORLD HEALTH REPORT, *supra* note 185, at 233. As Professor Fidler noted in relation to the shortage of vaccines for the H1N1 virus:

Developed countries placed large advance orders for 2009-H1N1 vaccine and bought virtually all the vaccine companies could manufacture. Developing countries and WHO identified the lack of equity in how developed countries were securing access to the vaccine. WHO entered talks with manufacturers and developed-country governments to secure some vaccine for developing countries, and WHO and the United Nations (UN) appealed for monetary donations to purchase vaccines and other supplies to help developing countries address the 2009-H1N1 virus. These efforts yielded donation pledges from manufacturers and developed countries, but the donations still left the developing world with limited supplies compared to developed countries, which would retain, even after donations, sufficient vaccine to cover their populations.

Fidler, *Negotiating Equitable Access*, *supra* note 186.

To make matters worse, for the reasons stated in the first virostory, many less developed countries have neither the capacity nor the resources to manufacture vaccines and antivirals themselves.<sup>189</sup> Because many vaccine manufacturers are located in developed countries, less developed countries are naturally and severely handicapped in a race to compete for vaccines. After all, “in a ‘global scramble for vaccine’, governments might block foreign access to their supplies, ban exports, nationalise the domestic production facilities, or refuse to share their vaccine.”<sup>190</sup> As David Fidler recounted in the H1N1 context, which did not break out until two years after Indonesia’s refusal to submit H5N1 samples to the WHO:

Canada awarded its vaccine contract to a Canadian company because it feared that foreign governments might restrict exports to Canada because of vaccine shortages within their territories. The Australian government made it clear to the Australian manufacturer CSL that it must fulfill the government’s domestic needs before exporting vaccine to the United States. The United States pledged on September 17, 2009, to donate 10% of its vaccine purchases to WHO, but on October 28, US Secretary of Health and Human Services Kathleen Sebelius stated that the United States would not donate H1N1 vaccine as promised until all at-risk Americans had access, because production problems had created shortages in the United States.<sup>191</sup>

Third, after Indonesia turned over their virus samples, there was no guarantee that the pharmaceutical companies would develop drugs that respond to the needs of the Indonesian population, as opposed to the more wealthy population in the developed world. Because viruses mutate all the time, drugs that target diseases found in developed countries do not always respond effectively to diseases found in their much poorer neighbors. In the HIV/AIDS context, for example, commentators lamented how the drugs

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189. As the Committee on Emerging Microbial Threats to Health of the Institute of Medicine noted in its widely-cited report, co-edited by Nobel Laureate Joshua Lederberg:

[F]ew vaccines are highly profitable and strict federal safety and efficacy requirements make the risk of failure a very real possibility. Vaccine developers must also take into account the extra costs that may arise from liability claims for injuries or deaths blamed on vaccines. This concern has forced a number of vaccine manufacturers out of the marketplace.

COMMITTEE ON EMERGING MICROBIAL THREATS TO HEALTH, INSTITUTE OF MEDICINE, EMERGING INFECTIONS: MICROBIAL THREATS TO HEALTH IN THE UNITED STATES 11 (1992) [hereinafter EMERGING INFECTIONS].

190. Kathryn White & Maria Banda, *The Role of Civil Society in Pandemic Preparedness*, in INNOVATION IN GLOBAL HEALTH GOVERNANCE, *supra* note 112, at 105, 117.

191. Fidler, *Negotiating Equitable Access*, *supra* note 186 (footnotes omitted).



available for the strand in developed countries do not always work well for patients in the less developed world.<sup>192</sup>

Fourth, Indonesia was understandably alarmed when the media reported that “Indonesian H5N1 viral sequences submitted earlier to WHO had been submitted to the Los Alamos National Laboratory in the US.”<sup>193</sup> Considering the laboratory’s involvement in national security-related research,<sup>194</sup> Indonesia expressed concern that the collected samples could be used to develop biological warfare. The Indonesian government also threatened to close down the U.S. Naval Medical Research Unit Two (“NAMRU-2”), a public health laboratory in Jakarta staffed by Indonesians and U.S. military scientists, accusing it of “profiteering off its ‘sovereign’ viruses to manufacturing the H5N1 bird flu in an alleged biological warfare scheme.”<sup>195</sup>

On its face, Indonesia’s charge seemed “outlandish,”<sup>196</sup> considering that the United States has been at the forefront of the combat against

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192. As Kelley Lee and Anthony Zwi recalled:

In the report of a meeting on HIV vaccines held by the Rockefeller Foundation at Bellagio, Italy in 1994, concerns were expressed that companies are “catering to the needs of the developed world” by focusing on “a small number of potential vaccine approaches”. This had included an emphasis on the HIV strain subtype B, which predominates in Europe and the US but not in low-income countries. One notable example has been trials in China and Thailand beginning in June 1993 of a potential HIV-B vaccine. In China the trials have been carried out by the US company United Biomedical with agreement of the Chinese government, while in Thailand it has been a joint project between the US and Thai armies. . . . [B]oth projects have been criticized on the grounds that the HIV-B virus generally does not occur in Asia.

Kelley Lee & Anthony Zwi, *A Global Political Economy Approach to AIDS: Ideology, Interests and Implications*, in *HEALTH IMPACTS OF GLOBALIZATION: TOWARDS GLOBAL GOVERNANCE* 13, 29 (Kelley Lee ed., 2003) [hereinafter *HEALTH IMPACTS OF GLOBALIZATION*] (citation omitted); see also *EMERGING INFECTIONS*, *supra* note 189, at 55 (discussing the HIV-1 and HIV-2 variants); Hammer, *supra* note 50, at 893 (“[C]linical needs in the third world may dictate a range of differences in terms of appropriate drug combinations, composition and dosages. These clinical differences can be consciously exploited to promote product differentiation between first- and third-world treatments.”).

193. William Aldis, *Health Security as a Public Health Concept: A Critical Analysis*, 23 *HEALTH POL’Y & PLANNING* 369, 374 n.1 (2008); accord *Indonesia Stops Announcing Bird Flu Deaths*, *supra* note 186 (“Indonesia stopped sharing bird flu samples with WHO in January 2007 after learning that some coveted data about the virus was being kept in a private database at a U.S. government laboratory in Los Alamos, New Mexico, and made accessible to only a handful of researchers.”).

194. See Aldis, *supra* note 193, at 374 n.1 (“This was distressing because this is understood to be a national security, not a public health, facility.”).

195. Holbrooke & Garrett, *supra* note 181.

196. *Id.*

bioterrorism and biological warfare. In reality, however, the United States did not have a clean record as far as medical experimentation on human subjects is concerned. In October 2010, the U.S. government revealed, shockingly, that “the government conducted medical experiments in the 1940s in which doctors infected soldiers, prisoners and mental patients in Guatemala with syphilis and other sexually transmitted diseases.”<sup>197</sup> The doctor who led these shameful experiments was also involved in the now-infamous medical experiment in Tuskegee, Alabama, in which “hundreds of African American men with late-stage syphilis were left untreated to study the disease between 1932 and 1972.”<sup>198</sup>

Finally, and quite importantly, Indonesia had international treaties on its side. Although the WHO Constitution and the 2005 International Health Regulations “do not contain specific, binding provisions on equitable access to vaccines and drugs for developing countries,”<sup>199</sup> Article 15.1 of the Convention on Biological Diversity (the “CBD”) “[r]ecogniz[es] the sovereign rights of States over their natural resources” and states that “the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.”<sup>200</sup> Article 10.1 of the International Treaty on Plant Genetic Resources for Food and Agriculture (“ITPGRFA”), which was developed under the auspices of the United Nations Food and Agriculture Organization, also “recognize[s] the sovereign rights of States over their own plant genetic resources for food and agriculture, including . . . the authority to determine access to those resources.”<sup>201</sup> Given the fact that the viruses constitute genetic resources, as stated explicitly in the Cartagena Protocol on Biosafety to the CBD,<sup>202</sup> these two treaties clearly support the strong sovereignty-based position taken by Indonesia.

From the standpoint of international law, Indonesia’s sovereignty claims are very interesting. As Professor Fidler observed, the country’s “willingness to leverage control over virus samples to provoke more

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197. Rob Stein, *U.S. Infected Guatemalans for STD Tests*, WASH. POST, Oct. 2, 2010, at A1. “The goal [of the studies] was to assess whether taking penicillin right after sex would prevent sexually transmitted infections.” *Id.*

198. *Id.*

199. Fidler, *Negotiating Equitable Access*, *supra* note 186.

200. Convention on Biological Diversity art. 15.1, June 5, 1992, 1760 U.N.T.S. 143 [hereinafter CBD].

201. International Treaty on Plant Genetic Resources for Food and Agriculture art. 10.1, Nov. 3, 2001, available at <ftp://ftp.fao.org/docrep/fao/011/i0510e/i0510e.pdf>.

202. See, e.g., Cartagena Protocol on Biosafety to the Convention on Biological Diversity art. 3(h), Jan. 29, 2000, 39 I.L.M. 1027 (“‘Living organism’ means any biological entity capable of transferring or replicating genetic material, including sterile organisms, *viruses* and viroids.” (emphasis added)).

multilateral responses to the access problem changed the political dynamics of this issue.”<sup>203</sup> Its effort in “fram[ing] their positions by using international law . . . [also] illustrated the importance and limitations of international law in global health diplomacy.”<sup>204</sup>

Notwithstanding Indonesia’s legal claims, both the CBD and the ITPGRFA include limitations and exceptions. Consider the CBD for example. Article 15.2 states that “[e]ach Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.”<sup>205</sup> In this case, not only did Indonesia fail to “create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties,” but it also arguably had “impose[d] restrictions that run counter to the objectives of this Convention.”<sup>206</sup> These objectives, as Article 1 states explicitly, “are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.”<sup>207</sup>

Using the CBD language to question the appropriateness of Indonesia’s actions, Professor Fidler wrote:

States parties to CBD have addressed avian influenza, not as a biological resource subject to CBD but as a threat to biological diversity. CBD discussions of avian influenza have considered its potential impact on wildlife, and the CBD process emphasized that surveillance is critical for combating avian influenza’s threat to biological diversity. Surveillance suffers without sharing information and samples of avian influenza viruses. Rather than protecting biological diversity, as mandated by CBD, Indonesia’s withholding virus samples from global surveillance efforts jeopardizes biological diversity in addition to population health.<sup>208</sup>

Because the spread of communicable diseases could undermine the CBD’s first two objectives, one could question whether Indonesia’s policy is in fact consistent with the Convention. One could also question whether Indonesia’s action would be in violation of Article 3, which prohibits States

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203. David P. Fidler, *Influenza Virus Samples, International Law, and Global Health Diplomacy*, 14 EMERGING INFECTIOUS DISEASES 88, 89 (2008) [hereinafter Fidler, *Influenza Virus Samples*].

204. *Id.* at 89–90.

205. CBD, *supra* note 200, art. 15.2.

206. *Id.*

207. *Id.* art. 1.

208. Fidler, *Influenza Virus Samples*, *supra* note 203, at 91 (footnote omitted).

from “caus[ing] damage to the environment of other States or of areas beyond the limits of national jurisdiction.”<sup>209</sup>

To complicate matters even further, Article 15.3 stipulates that, “[f]or the purpose of this Convention, the genetic resources being provided by a Contracting Party . . . are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.”<sup>210</sup> It therefore matters whether the claimed “sovereign” viruses actually originated in Indonesia or whether they originated elsewhere and merely entered the country to infect birds and chickens. While the former will result in protection under the CBD, the latter likely will not.

In retrospect, the debate about viral sovereignty is not new. For more than a decade, commentators have expressed concerns about the “biopiracy” of plant species and genetic resources, which occurs when patents are granted for naturally occurring products and indigenous practices that have existed for many centuries.<sup>211</sup> In theory, these products and practices are exempt from patent protection, for they are neither novel nor inventive. In practice, however, patents may be granted because many of these products and practices remain largely unknown to the general public.<sup>212</sup> As countries begin to focus on their obligations under the CBD, biosovereignty issues have quickly spilled over into the public health arena. Much of the rhetoric Indonesia deployed in the viral sovereignty debate actually originated from the biopiracy debate.

Even without the spillover from that debate, sovereignty issues come up all the time in the public health arena, especially when international obligations are implicated<sup>213</sup>—regardless of whether they relate to the early

209. CBD, *supra* note 200, art. 3; *see also* Mullis, *supra* note 181, at 957–58 (suggesting that Indonesia’s decision to withhold avian influenza samples could cause other countries sufficient harm to invoke Article 3 of the CBD).

210. CBD, *supra* note 200, art. 15.3.

211. “Biopiracy is seen as a new form of Western imperialism in which global seed and pharmaceutical corporations plunder the biodiversity and traditional knowledge of the developing world. Biopiracy is the unauthorized and uncompensated expropriation of genetic resources and traditional knowledge.” SUSAN K. SELL, *PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS* 140 (2003) (footnotes omitted). For discussions of biopiracy, *see* sources cited in Yu, *Cultural Relics*, *supra* note 175, at 481 n.266.

212. *See* IPR COMMISSION REPORT, *supra* note 29, at 81–82 (discussing the needs for and problems of traditional knowledge databases and digital libraries).

213. *See, e.g.*, Andrew F. Cooper et al., *Critical Cases in Global Health Innovation*, in *INNOVATION IN GLOBAL HEALTH GOVERNANCE*, *supra* note 112, at 3, 9 (“[N]ew sovereignty . . . arises as actors beyond nation-states and their intergovernmental institutions emerge as appropriate and effective centres of innovation and thus become legitimately embedded as authoritative institutions of global health governance.”); Arthur Kleinman & James L. Watson, *Introduction: SARS in Social and Historical Context*, in *SARS IN CHINA: PRELUDE TO*

international standards concerning hygiene and sanitation, to the right to health under international human rights treaties, or to newly created obligations under the 2005 International Health Regulations. Nevertheless, the claims of sovereignty in this case could pose serious health hazards to the nationals of other equally sovereign countries. As Holbrooke and Garrett rightly observed:

It is dangerous folly . . . to extend [the sovereignty notion] to viruses. If the concept of “viral sovereignty” had been applied to AIDS 25 years ago, we would not have central repositories of thousands of varieties of HIV today; these allow scientists to test drugs and vaccines against all the different strains of the AIDS virus. It is even more ludicrous to extend the sovereignty notion to viruses that, like flu, can be carried across international borders by migratory birds.<sup>214</sup>

In March 2007, health ministers of thirty countries gathered in Indonesia to draft the Jakarta Declaration on Responsible Practices for Sharing Avian Influenza Viruses and Resulting Benefits.<sup>215</sup> This declaration called upon the WHO “to convene the necessary meetings, initiate the critical processes and obtain the essential commitment of all stakeholders to establish the mechanisms for more open virus and information sharing and accessibility to avian influenza and other potential pandemic influenza vaccines for developing countries.”<sup>216</sup> Eight months later, at the Intergovernmental Meeting on Pandemic Influenza Preparedness, tensions resurfaced when “Indonesia reiterated the need for developing countries to have trust in a multilateral system that did not undermine their sovereign rights over biological resources (based on the CBD), nor disadvantage the health of people living in poor countries.”<sup>217</sup> In response, developed countries charged that “the stance taken by Indonesia was jeopardising global health

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PANDEMIC? 1, 1 (Arthur Kleinman & James Watson eds., 2005) [hereinafter SARS IN CHINA] (noting that the SARS epidemic “raised important questions about the role of national sovereignty in an increasingly interconnected world”).

214. Holbrooke & Garrett, *supra* note 181.

215. *Jakarta Declaration on Virus Sharing: A Strategic Step to More Equitable and Affordable Avian Flu Vaccines Distribution*, EUROBALI (Apr. 12, 2007), [http://eurobali.org/index.php?action=news&news\\_id=190](http://eurobali.org/index.php?action=news&news_id=190).

216. Chan Chee Khoo & Gilles de Wildt, *Developing Countries, Donor Leverage, and Access to Bird Flu Vaccines* 2 (U.N. Dep’t of Econ. & Soc. Affairs, Working Paper No. 41, 2007), available at [http://www.un.org/esa/desa/papers/2007/wp41\\_2007.pdf](http://www.un.org/esa/desa/papers/2007/wp41_2007.pdf).

217. ALTERNATIVE WORLD HEALTH REPORT, *supra* note 185, at 234.

security and violated the WHO's International Health Regulations."<sup>218</sup> Neither side was able to resolve the disagreement.

To make matters worse, other less developed countries have expressed similar concerns or have begun to follow Indonesia's lead in asserting claims of viral sovereignty. For instance, at the meeting of the WHO Executive Board in January 2007, a representative of Thailand noted:

We are sending our virus [samples] to the rich countries to produce antivirals and vaccines. And when the pandemic occurs, they survive and we die. . . . We are not opposed to the sharing of information and virus [samples], but on the condition that every country will have equal opportunity to get access to vaccines and antivirals if such a pandemic occurs.<sup>219</sup>

In May 2008, "Indian Health Minister A. Ramadoss [also] endorsed the concept [of viral sovereignty] in a dispute with Bangladesh."<sup>220</sup> Members of the Non-Aligned Movement ("NAM") further "agreed to consider formally endorsing the concept of 'viral sovereignty' at [a later] meeting."<sup>221</sup> A legacy of the Cold War, this Movement includes more than 100 less developed countries that seek not to align with the positions adopted by the major powers. On June 27, 2008, "[t]he NAM Ambassadors adopted the Declaration presented by Indonesia on avian flu, virus exchange and other benefits."<sup>222</sup>

Although the positions taken by Indonesia, India, and other NAM members were highly controversial, the wide support Indonesia received among less developed countries eventually led to the May 2007 adoption of Resolution WHA60.28, which recognizes both "the sovereign right of

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218. *Id.* Article 46 of the 2005 International Health Regulations, which covers "transport and handling of biological substances, reagents and materials for diagnostic purposes," provides: "States Parties shall, subject to national law and taking into account relevant international guidelines, facilitate the transport, entry, exit, processing and disposal of biological substances and diagnostic specimens, reagents and other diagnostic materials for verification and public health response purposes under these Regulations." Revision of the International Health Regulations, World Health Assembly Res. WHA58.3 (May 23, 2005); *see also* Lawson & Hocking, *supra* note 185, at 301 ("In implementing the International Health Regulations (2005) . . . members were 'urged' to 'disseminate to WHO collaborating centres information and relevant biological materials related to highly pathogenic avian influenza and other novel influenza strains in a timely and constituent manner.'" (quoting Application of the International Health Regulations (2005), World Health Assembly Res. WHA59.2 (May 26, 2006))).

219. FIDLER & GOSTIN, *supra* note 179, at 171.

220. Holbrooke & Garrett, *supra* note 181.

221. *Id.*

222. The Non-Aligned Movement, *15th Ministerial Conference of the Non-Aligned Movement—Report of the Chair of the Non-Aligned Movement: September 17, 2006–July 5, 2008*, NAM 2008/Doc.6, available at <http://nam.gov.ir/Portal/File/ShowFile.aspx?ID=679ba392-78cd-43be-8b4a-08a07ff0154a>.

States over their biological resources, and the importance of collective action to mitigate public health risks.”<sup>223</sup> That resolution further recognizes that “intellectual property rights do not and should not prevent Member States from taking measures to protect public health.”<sup>224</sup>

Three years later, the World Health Assembly adopted Resolution WHA64.5 outlining the Pandemic Influenza Preparedness (“PIP”) Framework.<sup>225</sup> Paragraph 5.1.2 of the PIP Framework specifically states that, by supplying biological materials to WHO collaborating centers and H5 reference laboratories, “Member States provide their consent for the onward transfer and use of PIP biological materials to institutions, organizations and entities, subject to provisions in the Standard Material Transfer Agreements [“SMTA”].”<sup>226</sup> Paragraph 5.4 introduces two types of these agreements: SMTA 1 “will be used to cover all transfers of PIP biological materials within the WHO GISRS for the duration of its applicability,”<sup>227</sup> while SMTA 2 “will cover all transfers of PIP biological materials to recipients” outside the WHO GISRS.<sup>228</sup>

In addition, Paragraph 6.9.1 states that the WHO Director-General “will establish and maintain a stockpile of vaccines for H5N1 and other influenza viruses with human pandemic potential and associated equipment, including

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223. Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits, pmbl., recital 4, World Health Assembly Res. WHA60.28 (May 23, 2007), available at [http://www.who.int/gb/ebwha/pdf\\_files/WHA60/A60\\_R28-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA60/A60_R28-en.pdf).

224. *Id.* pmbl., recital 5; see also Global Strategy and Plan of Action, *supra* note 107, ¶ 25 (“Intellectual property rights are an important incentive in the development of new health care products. However, this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain.”).

225. Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits, World Health Assembly Res. WHA64.5 (May 24, 2011) [hereinafter *PIP Framework*].

226. *Id.* ¶ 5.1.2. When the PIP Framework was proposed, the working group advancing the proposal “strongly recommend[ed] that the . . . Assembly consider the options regarding the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization.” *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Report by the Open-Ended Working Group of Member States on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*, Sixty-Fourth World Health Assembly, May 16–24, 2011, A64/8, provisional agenda item 13.1, at 3 (May 5, 2011). Adopted on October 29, 2010, the Nagoya Protocol aims to promote fair and equitable sharing of benefits arising from the utilization of genetic resources, thereby contributing to the conservation and the sustainable use of biological diversity. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization art. 1, Oct. 29, 2010, available at <http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>.

227. *PIP Framework*, *supra* note 225, ¶ 5.4.1. Article 6.1 of this SMTA explicitly states that “[n]either the Provider nor the Recipient should seek to obtain any intellectual property rights (IPRs) on the Materials.” *Id.* annex 1, art. 6.1.

228. *Id.* ¶ 5.4.2.

syringes, needles and applicators, consistent with expert guidance.”<sup>229</sup> As the Director-General reported in her 2013 biennial report: “During May 2011–May 2012, [she] initiated discussions with four large influenza vaccine manufacturers to commence the process to sign SMTA 2s. The PIP Secretariat has also provided information on the SMTA 2 and the process to conclude it to over 30 prospective recipients of PIP biological materials.”<sup>230</sup>

Finally, Paragraph 6.13.1, which covers technology transfer, states that the Director-General “will continue to work closely with Member States and influenza vaccine manufacturers to implement the WHO Global Pandemic Influenza Action Plan to Increase Vaccine Supply, including its strategies to build new production facilities in developing and/or industrialized countries and through transfer of technology, skills and know-how.”<sup>231</sup> Paragraph 6.13.2 further states that “Member States should urge influenza vaccine, diagnostic and pharmaceutical manufacturers to make specific efforts to transfer these technologies to other countries, particularly developing countries, as appropriate.”<sup>232</sup>

In sum, compared with the first two virostories, the third story shows more radical developments. Instead of relying on adjustments to the patent system or taking full advantage of that system, countries advance new concepts to challenge the whole system. Building on efforts developed over the biopiracy debate, Indonesia, India, and other NAM members successfully underscored the importance of maintaining sovereignty over their virological materials. Luckily, the PIP Framework and its two SMTAs

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229. *Id.* ¶ 6.9.1.

230. WHO Executive Board, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Pandemic Influenza Preparedness Framework 2013 Biennial Report—Report by the Director-General*, at 20, WHO Doc. EB132/16 (Nov. 16, 2012). As elaborated in a “Questions and Answers” document:

The process to negotiate and sign SMTA 2 with individual manufacturers and entities will start in 2012 and is anticipated to be a multi-year process taking place in several phases. WHO will start by developing template agreements for the different types of benefit sharing foreseen under the PIP Framework (donations; pre-purchase of vaccine or antiviral medicines; licenses for intellectual property rights). Following this, WHO will contact influenza vaccine manufacturers first, in order to begin negotiation of individual agreements. Later, WHO will work with other recipients so that in time, all non-GISRS recipients of PIP biological materials have signed an SMTA2 with WHO.

WHO, *Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (PIP Framework): Questions and Answers* 9, (Sept. 2011), available at [http://www.who.int/influenza/pip/PIP\\_FQA\\_Nov\\_2011.pdf](http://www.who.int/influenza/pip/PIP_FQA_Nov_2011.pdf).

231. *PIP Framework*, *supra* note 225, ¶ 6.13.1.

232. *Id.* ¶ 6.13.2.



were established in time to prevent the global health system from being seriously undermined.

#### IV. TOWARD A NEW INTEGRATED APPROACH

The three stories discussed earlier in this Article cover viruses that have serious impacts on global public health. They not only provide important lessons about the changing intellectual property system, but also raise important questions about how to analyze issues lying at the intersection of intellectual property, public health, human rights, and economic development.<sup>233</sup> For example, should our analysis be different if the patented medicines were introduced to treat communicable diseases, which could quickly spread from one country to another? Should the international intellectual property norm-setting process be modified in light of the growing participation of health NGOs and pro-consumer activists, which are usually unrepresented or underrepresented in state-based fora? Are there alternative innovation models or policy options that go beyond incremental adjustments to existing intellectual property standards?

To help analyze these issues and develop new legal standards and policy recommendations, Part IV.A underscores the need for a new integrated approach to setting international intellectual property norms. Specifically, it calls for analysis that is holistic, multidisciplinary, globally-oriented, and empirically based. Part IV.B then draws seven important lessons from the three virostories discussed in the Article. With a focus on global governance, this Part discusses these lessons in the context of three areas in which the international intellectual property norm-setting process can be reformed: (1) negotiation gains; (2) the negotiation process; and (3) negotiated outcomes. Among the concrete examples that will be further explored are the recent and ongoing efforts to reform the international patent system (including the effort to ratify Article 31*bis* of the TRIPS Agreement), the introduction of higher international enforcement standards in ACTA<sup>234</sup> and the TPP,<sup>235</sup> and the continued negotiation of intellectual property chapters in bilateral, plurilateral, and regional trade agreements.<sup>236</sup>

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233. See Peter K. Yu, *Intellectual Property Training and Education for Development*, 28 AM. U. INT'L L. REV. 311, 328 (2012) [hereinafter Yu, *Intellectual Property Training*] ("[I]ntellectual property training and educational programs should feature inter- and multi-disciplinary perspectives."); Yu, *The International Enclosure Movement*, *supra* note 14, at 855 ("[I]f we are to effectively address the public health crises in less developed countries, it is very important to take a holistic perspective and target each aspect of the problem, because efforts that succeed in addressing one aspect may alleviate the impact of the others.").

234. For the Author's earlier discussions of ACTA, see generally Peter K. Yu, *ACTA and Its Complex Politics*, 3 WIPO J. 1 (2011); Peter K. Yu, *Enforcement, Enforcement, What*

Although the scope and length of this Article do not allow for a full discussion of the application of the proposed integrated approach to other developments in the area intersecting intellectual property and public health, it is worth noting that a deeper analysis using this approach could provide new and important insights. Some of the recent developments on which the proposed approach could shed light include India and Brazil's WTO dispute with the European Union and the Netherlands over the seizure of in-transit generic drugs,<sup>237</sup> Novartis' unsuccessful challenge to section 3(d) of the Indian Patents (Amendment) Act of 2005 before the Indian Supreme Court,<sup>238</sup> the tobacco industry's ongoing efforts to use the WTO and bilateral investment agreements to challenge plain packaging

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*Enforcement?*, 52 IDEA 239 (2012) [hereinafter Yu, *Enforcement, Enforcement*]; Peter K. Yu, *Six Secret (and Now Open) Fears of ACTA*, 64 SMU L. REV. 975 (2011) [hereinafter Yu, *Six Secret Fears*].

235. For discussions of the TPP, see generally NO ORDINARY DEAL: UNMASKING THE TRANS-PACIFIC PARTNERSHIP FREE TRADE AGREEMENT (Jane Kelsey ed., 2011); THE TRANS-PACIFIC PARTNERSHIP: A QUEST FOR A TWENTY-FIRST CENTURY TRADE AGREEMENT (C.L. Lim et al. eds., 2012); Meredith Kolsky Lewis, *The Trans-Pacific Partnership: New Paradigm or Wolf in Sheep's Clothing?*, 34 B.C. INT'L & COMP. L. REV. 27 (2011); Peter K. Yu, *The Alphabet Soup of Transborder Intellectual Property Enforcement*, 60 DRAKE L. REV. DISCOURSE 16, 24–28 (2012).

236. See AUSFTA, *supra* note 32, ch. 17; Free Trade Agreement Between the Republic of Korea and the United States of America, S. Korea-U.S., ch. 18, June 30, 2007, available at [http://www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset\\_upload\\_file273\\_12717.pdf](http://www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file273_12717.pdf); see also Peter K. Yu, *Trade Agreement Cats and the Digital Technology Mouse*, in SCIENCE AND TECHNOLOGY IN INTERNATIONAL ECONOMIC LAW: BALANCING COMPETING INTERESTS 185, 193–97 (Bryan Mercurio & Ni Kuei-Jung eds., 2014) (discussing these chapters).

237. See sources cited *supra* note 104.

238. See Patralekha Chatterjee, *Novartis Loses Patent Bid: Lessons from India's 3(d) Experience*, INTELL. PROP. WATCH (Apr. 1, 2013, 11:41 PM), <http://www.ip-watch.org/2013/04/01/novartis-loses-patent-bid-lessons-from-indias-3d-experience/>; see also Rachel Marusak Hermann, *Novartis Before India's Supreme Court: What's Really at Stake?*, INTELL. PROP. WATCH (Mar. 2, 2012, 12:05 PM), <http://www.ip-watch.org/2012/03/02/novartis-before-india%E2%80%99s-supreme-court-what%E2%80%99s-really-at-stake>. Novartis made that challenge following the rejection of its application concerning the anti-cancer drug Gleevec/Glivec (imatinib mesilate). Section 3(d) of that law specifically prevents patent protection from being granted to

the mere discovery of a new form of a known substance which does not result in increased efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such process results in a new product or employs at least one new reactant.

The Patents (Amendment) Act, No. 15 of 2005, § 3(d), India Code (2005); see also Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CALIF. L. REV. 1571, 1590–98 (2009) (discussing section 3(d) of the Indian Patents (Amendment) Act of 2005).

legislation,<sup>239</sup> and Eli Lilly's recent \$500 million complaint against Canada under Chapter 11 of the North American Free Trade Agreement (NAFTA) following the Canadian courts' invalidation of its drug patents.<sup>240</sup>

To some extent, many of these developments remind us of the disastrous lawsuit the South African Pharmaceutical Manufacturers Association and thirty-nine mostly multinational pharmaceutical companies brought against Nelson Mandela's government in February 1998.<sup>241</sup> Signed into law by the late President Mandela, the Medicines and Related Substances Control Amendment Act 1997 "introduce[d] a legal framework to increase the availability of affordable medicines in South Africa . . . [by providing for] generic substitution of off-patent medicines, transparent pricing for all medicines, and the parallel importation of patented medicines."<sup>242</sup> The brand name pharmaceutical industry's challenge, and the subsequent backing of the United States Trade Representative ("USTR") and the European Commission,<sup>243</sup> not only created a public relations disaster for the industry, but eventually led to the adoption of the Doha Declaration.<sup>244</sup>

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239. See Request for Consultations by Ukraine, *Australia—Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WT/DS434/1 (Mar. 15, 2012); Request for Consultations by Honduras, *Australia—Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WT/DS435/1 (Apr. 10, 2012). For discussions of these challenges, see generally PUBLIC HEALTH AND PLAIN PACKAGING OF CIGARETTES: LEGAL ISSUES (Tania Voon et al. eds., 2012); Henning Grosse Ruse-Khan, *A Conflict-of-Laws Approach to Competing Rationalities in International Law: The Case of Plain Packaging Between IP, Trade, Investment and Health* (Max Planck Inst. for Intellectual Prop. & Competition Law, Research Paper No. 13-05, 2013), available at <http://ssrn.com/abstract=2204980>.

240. See Kazi Stastna, *Eli Lilly Files \$500M NAFTA Suit Against Canada over Drug Patents*, CBC NEWS (Sept. 13, 2013, 8:44 PM), <http://www.cbc.ca/news/business/eli-lilly-files-500m-nafta-suit-against-canada-over-drug-patents-1.1829854>; see also Henning Grosse Ruse-Khan, *Investor-State Arbitration to Challenge Host State Compliance with International IP Treaties?*, INT'L ECON. L. & POL'Y BLOG (Dec. 11, 2012, 11:07 AM), <http://worldtradelaw.typepad.com/ielpblog/2012/12/investor-state-arbitration-to-challenge-host-state-compliance-with-international-ip-treaties.html> (discussing this notice).

241. See 't Hoen, *TRIPS, Pharmaceutical Patents*, *supra* note 64, at 30–31 (discussing the lawsuit).

242. *Id.* at 30.

243. The United States government backed the industry by putting South Africa on the Section 301 Watch List and announcing the suspension of its Generalized System of Preferences benefits. See SELL, *supra* note 211, at 151; see also 't Hoen, *TRIPS, Pharmaceutical Patents*, *supra* note 64, at 30–31 (discussing the support the brand name pharmaceutical industry received from both the USTR and the European Commission).

244. The ill-advised lawsuit also led to the Clinton administration's adoption of Executive Order 13,155, which enables countries in sub-Saharan Africa to enhance access to HIV/AIDS medicines and related medical technologies without fear of trade retaliation. Exec. Order No. 13,155, 65 Fed. Reg. 30,521 (May 12, 2000).

Paragraph 6 of this Declaration, in turn, precipitated the efforts to amend the TRIPS Agreement by adding Article 31*bis*.<sup>245</sup> Paragraph 7 also extended the transition period for the protection of pharmaceutical patents and undisclosed clinical trial data,<sup>246</sup> paving the way for two later extensions for least developed countries in all other areas.<sup>247</sup> If these changes are not far-reaching enough, the industry's ill-advised lawsuit has changed the tone of the entire global intellectual property debate.<sup>248</sup> Given the seemingly repeat efforts of rights holders in restricting access to patented medicines and the less developed countries' continued difficulty in obtaining this much-needed access, the development of a new approach is not only in order, but urgently needed.

#### A. *The Need for Holistic, Multidisciplinary, Socio-legal Analysis*

When intellectual property laws and policies come into existence, they tend to be established in clinical isolation from developments in other disciplines and issue areas. However, as the three stories discussed earlier in this Article have shown, what happens in the intellectual property area could easily spill over into other areas—in this case, global health governance. As the scope of intellectual property rights continues to expand, the intellectual property debate no longer concerns only technical details about intellectual property laws and policies. As a result, an integrated approach is needed to help us better understand the global health implications of these laws and policies.

The proposed approach is also important in light of the continued forum-manipulative activities conducted by both developed and less developed countries.<sup>249</sup> Because such activities have moved international intellectual property discussions to fora that traditionally do not cover the subject

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245. See Doha Declaration, *supra* note 73, ¶ 6.

246. See *id.*

247. See *supra* text accompanying notes 22–23.

248. See, e.g., SELL, *supra* note 211, at 181 (observing that “[t]he HIV/AIDS pandemic was a contingency that sped up the revelation of the negative consequences of TRIPS”); Ruth Mayne, *The Global Campaign on Patents and Access to Medicines: An Oxfam Perspective*, in GLOBAL INTELLECTUAL PROPERTY RIGHTS: KNOWLEDGE, ACCESS AND DEVELOPMENT 244, 249 (Peter Drahos & Ruth Mayne eds., 2002) (noting that “[t]he South African government’s decision to fight the case was a critical factor in generating global media interest”); Yu, *Access to Medicines*, *supra* note 67, at 355 (arguing that “the campaign on access to drugs, to which South Africa made an important contribution, provides a major turning point in the TRIPS debate”).

249. For discussions of these activities, see sources cited in Yu, *Intellectual Property Training*, *supra* note 233, at 325 n.59.

matter,<sup>250</sup> new issues, ideas, textual language, values, and arguments have begun to emerge in the debate on intellectual property laws and policies. Drawing on these new developments, commentators have called for policymakers to undertake a more holistic assessment of the need for legal and policy reforms.<sup>251</sup>

Consider the HIV/AIDS pandemic for example. The adjustment of intellectual property laws and policies alone is insufficient to address problems created by this pandemic. Other contributing factors include “inadequate healthcare and drug delivery; lack of medical infrastructure and research capabilities; insufficient sex education and drug control; ill-advised trade, investment and financial policies; political unrests and civil wars; bribery and corruption; abject poverty and colonization-induced underdevelopment.”<sup>252</sup> The more comprehensive the analysis is, the better the understanding of the interplay among these factors will be, and the more successful adjustments policymakers will make to their priorities.

The push for a more holistic approach, indeed, has opened up the possibility for experts from different disciplines to interact with each other, at both the policy and discursive levels. As the discussion of global health governance becomes more inter- and multi-disciplinary, experts have begun to pay greater attention to the multifaceted interfaces between and among the different international regimes.<sup>253</sup> These interfaces are not only present in places where the regimes intersect, but they can also be created through legal linkages, technical cooperation, institutional interplay, and political alliances. The emphasis on these interfaces makes good sense. After all, “[t]he process by which an infectious disease emerges and is recognized and responded to can be complex.”<sup>254</sup>

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250. See Yu, *Two Development Agendas*, *supra* note 92, at 522–40 (discussing how less developed countries have actively pushed for intellectual property reforms in not only WIPO and the WTO, but also other fora governing public health, human rights, biological diversity, food and agriculture, and information and communications).

251. See Jonathan Mann, *AIDS, in ONE WORLD: THE HEALTH AND SURVIVAL OF THE HUMAN SPECIES IN THE 21ST CENTURY* 75, 79 (Robert Lanza ed., 2003) (“It is now clear that HIV/AIDS is as much about society as about a virus.”).

252. Yu, *Rugged Road Ahead*, *supra* note 102, at 227; accord Richard Dogson & Kelly Lee, *Global Health Governance: A Conceptual Review*, in *GLOBAL GOVERNANCE: CRITICAL PERSPECTIVES* 92, 92 (Rorden Wilkinson & Steve Hughes eds., 2002) [hereinafter *GLOBAL GOVERNANCE*] (“Part of the increasing health risk and the lack of an adequate local, national and global response is caused by factors outside the health sector—trade and investment policies; debt burden and international development assistance.”).

253. See Sonja Bartsch et al., *Interfaces: A Concept for the Analysis of Global Health Governance*, in *FIGHT AGAINST HIV/AIDS*, *supra* note 17, at 18 (advancing the concept and logic of “interfaces” for analyzing global governance).

254. *EMERGING INFECTIONS*, *supra* note 189, at 113.

Because this integrated approach can be realized through a large number of practices, this Section provides three examples. The first concerns the use of the approach to reframe the international patent debate. Such reframing is likely to have significant implications for intellectual property laws and policies. As Peter Drahos and John Braithwaite reminded us, “Had TRIPS been framed as a public health issue, the anxiety of mass publics in the US and other Western states might have become a factor in destabilising the consensus that US business elites had built around TRIPS.”<sup>255</sup> Likewise, a growing number of commentators are now paying attention to the framing of the domestic and international intellectual property debates.<sup>256</sup>

Indeed, had this Article been written from the intellectual property perspective, as opposed to one lying at the intersection of intellectual property and public health, it likely would have read very differently. Instead of highlighting the less developed countries’ increased frustration with the international patent system in the public health arena, an article written from the intellectual property perspective alone would focus on the widespread problem of piracy and counterfeiting, the low enforcement standards of the TRIPS Agreement,<sup>257</sup> the lack of compliance with these standards in many less developed countries, and the need for efforts such as the WHO International Medical Products Anti-Counterfeiting Taskforce (IMPACT).<sup>258</sup>

The second example concerns efforts to bring together expertise from multiple disciplines. As commentators repeatedly noted, there is a strong and ever-growing need for collaboration between government officials involved in various policy areas<sup>259</sup>—in this case, public health personnel and intellectual property policymakers.<sup>260</sup> Consider, for example, the Brazilian National Health Surveillance Agency (“ANVISA”), which Peter

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255. JOHN BRAITHWAITE & PETER DRAHOS, *GLOBAL BUSINESS REGULATION* 576 (2000).

256. For discussions of the importance of framing and reframing issues in the international intellectual property debate, see sources cited in Yu, *Objectives and Principles*, *supra* note 134, at 1038 n.270.

257. See Yu, *TRIPS and Its Achilles’ Heel*, *supra* note 57, at 483–504 (discussing the low TRIPS enforcement standards).

258. See Kaitlin Mara, *Hope for Consensus on WHO and Counterfeits Moves to May Assembly*, INTELL. PROP. WATCH (Jan. 27, 2009, 10:33 AM), <http://www.ip-watch.org/2009/01/27/hope-for-consensus-on-who-and-counterfeits-moves-to-may-assembly/> (discussing the controversy surrounding IMPACT of the WHO).

259. See generally CAROLYN DEERE, *THE IMPLEMENTATION GAME: THE TRIPS AGREEMENT AND THE GLOBAL POLITICS OF INTELLECTUAL PROPERTY REFORM IN DEVELOPING COUNTRIES* 211–14 (2009) (discussing government coordination in making intellectual property decisions).

260. See, e.g., Peter Drahos, “Trust Me”: *Patent Offices in Developing Countries*, 34 AM. J.L. & MED. 151, 169–70 (2008) [hereinafter Drahos, “Trust Me”]; Yu, *Access to Medicines*, *supra* note 67, at 378.

Drahos used to illustrate the many benefits provided by greater coordination between patent offices and health and medical experts in assessing an invention's contribution to innovation and health welfare.<sup>261</sup> As he explained, health and medical experts are likely to be in a much better position than patent examiners to make such an assessment.<sup>262</sup>

Drawing on Professor Drahos's example, I went further to suggest that the ANIVSA model could be used to facilitate greater cooperation between intellectual property offices *in the South* and health and medical experts and related NGOs *in the North*.<sup>263</sup> Sadly, despite the immense potential of the ANVISA model, the Brazilian government recently greatly curtailed the agency's efforts,<sup>264</sup> due in part to the continued conflict between ANVISA and the Brazilian industrial property agency (INPI).<sup>265</sup> As of this writing, it is unclear how effective ANVISA will continue to be in the patent area,<sup>266</sup>

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261. See Drahos, "Trust Me," *supra* note 260, at 169–70.

262. As he elaborated:

The Brazilian model is worth close study by other developing countries. It is a preventive strategy that avoids the high costs of attempting to remove patents that have been granted. It is also an integrative regulatory strategy. It links patentability criteria in the area of pharmaceuticals to the goal of welfare-enhancing innovation in the health sector. One of the real concerns with pharmaceutical patenting has been that patent offices are granting patents over essentially trivial steps in the innovation process. The reasons for this are complex, having to do with the incentives facing patent offices, the narrow training of patent examiners, the fact that patent examiners are not researchers, and that they are not integrated into communities of public health experts that know about what constitutes real innovation in a given field. From the perspective of the patent social contract, the grant of patents over trivial or obvious steps in the pharmaceutical innovation process constitutes a welfare loss to society. Involving public health experts in the process of patent administration is one way of helping to ensure that the patent social contract functions as it should in the health sector.

*Id.* at 169–70 (footnotes omitted).

263. See Yu, *Access to Medicines*, *supra* note 67, at 378.

264. See Felipe Carvalho, *Brazil and the Defence of Public Health: Do as I Say, Not as I Do*, INTELL. PROP. WATCH (Feb. 17, 2011, 3:30 PM), <http://www.ip-watch.org/weblog/2011/02/17/brazil-and-the-defence-of-public-health-do-as-i-say-not-as-i-do/> (reporting the October 2010 decision of the Advocacia Geral da União that undermined ANVISA's prior consent mechanism (*anuência prévia*)).

265. For discussions of this conflict, see generally Kenneth C. Shadlen, *The Political Contradictions of Incremental Innovation: Lessons from Pharmaceutical Patent Examination in Brazil*, 39 POL. & SOC'Y 143 (2011); Kenneth C. Shadlen, *The Rise and Fall of "Prior Consent" in Brazil*, 3 WIPO J. 103 (2011) [hereinafter Shadlen, *Rise and Fall*].

266. See Shadlen, *Rise and Fall*, *supra* note 265, at 108 ("In fact, as of late 2011 prior consent appears, for all practical purposes, to be dead.").

although Brazil is currently reviewing ANVISA's role in the patent examination process.<sup>267</sup>

To some extent, the need for collaboration across disciplines reminds us of a key lesson from the SARS outbreak. As anthropology professors Arthur Kleinman and James Watson rightly pointed out:

Seen in the context of avian flu and the major outbreaks of flu in the twentieth century—most of which appear to have originated in south China—the SARS crisis suggests that a new approach to understanding human epidemics must be found. Virologists need to work in teams consisting of ecologists, biologists, soil scientists, economists, political scientists, demographers, epidemiologists, anthropologists, and ethicists. This is the only way we can hope to understand the intersection of ecological, social, and biological processes that underline emergent infectious diseases. At issue here are the migration of waterfowl, the intensive cultivation of ducks, chickens, and pigs in settings of dense human habitation, trade in and sale of wild animals, the migration of workers and the complexities of local cultural practices.<sup>268</sup>

Within governments, “more departments are [now] becoming involved, including the powerful departments for agriculture, finance, development, trade, foreign policy, national security, and national intelligence, as well as the traditionally low-ranking and isolated ones responsible for environment and for health.”<sup>269</sup>

The third example concerns the development of empirical studies that can help holistically assess the strengths and weaknesses of intellectual property laws and policies. An empirically based approach would not only allow policymakers to better assess the full costs and benefits of newly introduced measures, but would also prevent the assessment from being captured by those who would directly benefit from heightened standards of intellectual property protection and enforcement.

In recent years, impact assessments have been widely endorsed in the areas of human rights, public health, and biological diversity.<sup>270</sup>

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267. See *Open Letter from Global Academics in Support of Proposal to Amend Brazil's Patent Law to Take Advantage of TRIPS-Compliant Flexibilities*, INFOJUSTICE.ORG, <http://infojustice.org/support-brazil> (last visited Nov. 4, 2013) (calling for ANVISA's involvement in Brazil's patent examination process).

268. Kleinman & Watson, *supra* note 213, at 14.

269. Kirton & Cooper, *Innovation in Global Health Governance*, *supra* note 166, at 314.

270. See, e.g., CBD, *supra* note 200, art. 14(1)(a) (requiring contracting parties to “[i]ntroduce appropriate procedures requiring environmental impact assessment of its proposed projects that are likely to have significant adverse effects on biological diversity with a view to avoiding or minimizing such effects and, where appropriate, allow for public participation in



Assessment, evaluation, and impact studies also constitute one of the six clusters of recommendations adopted as part of the WIPO Development Agenda in October 2007.<sup>271</sup> To ensure more accurate assessments, countries should deploy holistic impact assessments that involve institutional cooperation across sectors and agencies. Preferably, these assessments will be conducted before the introduction of new forms of protection.<sup>272</sup> If such assessments cannot be undertaken at that time—for example, as a result of heavy external pressure from developed country governments—assessments should still be conducted following the introduction of new standards or measures, perhaps after a specified period of time.<sup>273</sup>

In sum, there are many different ways to develop a new integrated approach for international norm-setting that is holistic, multidisciplinary, globally oriented, and empirically based. To provide further illustrations, the next three sections draw seven different lessons from the three virostories discussed in this Article. The first two lessons concern the need for developed countries to rethink their negotiation gains and for less

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such procedures”); Comm. on Econ., Soc. & Cultural Rights, *General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from Any Scientific, Literary or Artistic Production of Which He or She Is the Author (Article 15, Paragraph 1(c), of the Covenant)*, ¶ 35, U.N. Doc. E/C.12/GC/17 (Jan. 12, 2006) [hereinafter *General Comment No. 17*] (“States parties should . . . consider undertaking human rights impact assessments prior to the adoption and after a period of implementation of legislation for the protection of the moral and material interests resulting from one’s scientific, literary or artistic productions.”); CIPRI PH REPORT, *supra* note 158, at 10 (stating that “[h]ealth policies, as well as inter alia those addressing trade, the environment and commerce, should be equally subject to assessments as to their impact on the right to health”); JAMES HARRISON, THE HUMAN RIGHTS IMPACT OF THE WORLD TRADE ORGANISATION 228 (2007) (“Systematic environmental assessments of trade agreements are relatively common. Norway, the US and Canada all carry out reviews of the environmental impact of trade policies which include some international impact assessment, as do the United Nations Environment Programme and World Wildlife Fund.”).

271. See *The 45 Adopted Recommendations Under the WIPO Development Agenda*, WORLD INTEL. PROP. ORG., <http://www.wipo.int/ip-development/en/agenda/recommendations.html> (last visited Nov. 4, 2013) (outlining recommendations concerning assessment, evaluation, and impact studies in cluster D).

272. *Ex ante* reviews tend to be more effective than *ex post* reviews. See Peter K. Yu, *The Political Economy of Data Protection*, 84 CHI.-KENT L. REV. 777, 799–801 (2010) [hereinafter Yu, *Political Economy*] (criticizing the EU *ex post* evaluation of its Database Directive and distributing recommendations based on such an evaluation); see also James Boyle, *Two Database Cheers for the EU*, FIN. TIMES (Jan. 2, 2006, 5:31 PM), <http://www.ft.com/cms/s/99610a50-7bb2-11da-ab8e-0000779e2340.html> (discussing the European Commission’s first report on the Directive).

273. Cf. HARRISON, *supra* note 270, at 229 (“The EU methodology . . . contains provisions requiring ‘ex post monitoring, evaluation and follow up of trade agreements’ so that ongoing impacts of trade agreements can be evaluated once the agreement in question is actually in force.”).

developed countries to better articulate their bargain offers. The next three focus on the changing nature of the international norm-setting process. The final two lessons cover the possibility for a wide and diverse array of negotiated outcomes.

## *B. Negotiation Gains*

### 1. Lesson #1: Communicable Diseases

Intellectual property agreements are established through international negotiations. When countries negotiate these agreements, they often are reluctant to provide concessions to other parties unless they gain something in return. Although there are many different narratives about the origin of the TRIPS Agreement,<sup>274</sup> the bargain narrative remains the most widely accepted.<sup>275</sup> Under this narrative, developed countries received stronger intellectual property protection and greater market access. In return, less developed countries obtained lower tariffs on textiles and agriculture and protection via the mandatory WTO dispute settlement process against unilateral sanctions imposed by the United States and other developed countries. Viewed through the bargain narrative, the TRIPS Agreement was a well-negotiated compromise between developed and less developed countries.

While a “quid pro quo” approach is understandable, bargaining has not always been easy within the WTO. Consider the current Doha Round negotiations. Although developed country governments continue to demand liberalization in trade areas that are not yet covered by existing WTO agreements, there are very few remaining areas in which less developed countries could offer concessions. Even worse, because the high TRIPS standards often ignore the needs, interests, conditions, and priorities of the latter group of countries, the legitimacy of the TRIPS Agreement, and by extension the WTO, have now been called into question.<sup>276</sup>

Sadly, despite this deepening legitimacy crisis, developed country negotiators continue to demand concessions in exchange for proposals that

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274. See Peter K. Yu, *TRIPs and Its Discontents*, 10 MARQ. INTELL. PROP. L. REV. 369, 371–79 (2006) (discussing four dominant narratives concerning the origins of the TRIPS Agreement). The three other narratives are the coercion narrative, the ignorance narrative, and the self-interest narrative. *Id.* at 373–79.

275. See *id.* at 371–73 (discussing the bargain narrative of the TRIPS Agreement).

276. See Yu, *Objectives and Principles*, *supra* note 134, at 1024; see also SELL, *supra* note 211, at 173 (“The shaky foundations of [the TRIPS] regime raise important concerns about accountability and legitimacy.”).

strengthen the development dimension of the TRIPS Agreement. This point is not hard to understand from the standpoint of domestic politics. As Robert Putnam pointed out in a path-breaking article, international treaty negotiations involved two different political games: one domestic and one international.<sup>277</sup> If negotiators are to be successful, they need to get buy-in at both levels. What these negotiators fail to realize, however, is that rebuilding the legitimacy of the TRIPS Agreement is just as important a gain as obtaining new concessions in trade and trade-related areas.

Fortunately for the protection of public health, two additional sets of negotiation gains exist to accelerate the negotiations between developed and less developed countries. This section will explore the first set of negotiation gains, and the next section will address the second set. Although developed country negotiators have hitherto not appreciated any of these gains, an integrated approach would show that the gains are not to be ignored.

The first set of negotiation gains is unique to communicable diseases. It focuses on the immense health benefits provided by addressing the access-to-medicines problems in less developed countries. As commentators have widely noted, the provision of public health is a public good that is often undersupplied. In fact, many less developed countries lack the incentive to provide extra control when they know full well that the costs of underprotection—and by extension the costs of interruptions to global flows of trade and commerce—would be externalized to developed countries and other parts of the world. As Eric Posner remarked in relation to the SARS outbreak:

Quick detection and quarantine in a state of origin would benefit victim states—but an originating state has few incentives to be vigilant on behalf of other states, since it does not bear the full cost of the pandemic. States of origin may in fact have an incentive to hide the outbreak, so as not to scare off foreign investment and tourism, until the pandemic becomes uncontrollable and can no longer be hidden in any event. China covered up the SARS outbreak at first. Sharing of early evidence of an outbreak would clearly be collectively beneficial, but individual state interests are in conflict.<sup>278</sup>

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277. See generally Robert D. Putnam, *Diplomacy and Domestic Politics: The Logic of Two-Level Games*, 42 INT'L ORG. 427 (1988) (discussing the two-level game involved in international treaty negotiations). For a collection of essays inspired by this highly influential article, see DOUBLE-EDGED DIPLOMACY: INTERNATIONAL BARGAINING AND DOMESTIC POLITICS (Peter B. Evans, Harold K. Jacobson & Robert D. Putnam eds., 1993).

278. ERIC A. POSNER, THE PERILS OF GLOBAL LEGALISM 5 (2009).

Increasingly, countries need to view the protection of public health as a security issue.<sup>279</sup> To some extent, what happens in the less developed world could easily spill over into the developed world. Although AIDS could be traced back to contact with primates in Africa decades ago,<sup>280</sup> it now has affected both developed and less developed countries. In fact, because the WHO mischaracterized HIV/AIDS as a developed country health problem in the early days of the disease, it “missed the initial opportunity to act against the rapid spread of the epidemic in Africa and also in the Caribbean and to contain its explosion into a global problem.”<sup>281</sup>

Likewise, even though SARS has been traced to wild animals in China,<sup>282</sup> it has affected a large number of countries in both the developed and less developed worlds. In the wake of the SARS outbreak, it is no surprise that the WHO, national governments, and health professionals have been exceedingly cautious in handling H5N1 and H1N1. We may never know whether these two viruses would have spread as quickly as SARS if these precautions had not been taken, but it is hard to ignore the increasing global nature of health hazards caused by communicable diseases. As the 2007 *World Health Report* reminded us, “an outbreak or epidemic in any one part of the world is only a few hours away from becoming an imminent threat somewhere else.”<sup>283</sup>

In sum, in cases involving this type of disease, the intellectual property debate can be easily linked to the ongoing debate about global health as a security issue. In doing so, it could help elevate the political status of the

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279. See S.C. Res. 1308, recital 11, U.N. Doc. S/RES/1308 (July 17, 2000) (“*Stressing that the HIV/AIDS pandemic, if unchecked, may pose a risk to stability and security . . .*”); LISK, *supra* note 17, at 59–68 (discussing HIV/AIDS as a security threat); Dennis Altman, *Understanding HIV/AIDS as a Global Security Issue*, in *HEALTH IMPACTS OF GLOBALIZATION*, *supra* note 192, at 33 (noting the need to understand HIV/AIDS as a global security issue); Ilona Kickbusch, *Foreword: Governing Interdependence*, in *FIGHT AGAINST HIV/AIDS*, *supra* note 17, at x, xi (“[T]he rapid spread of HIV/AIDS was no longer considered just a health risk, it was defined as a security concern of global dimensions.”); Kelley Lee, *Understandings of Global Health Governance: The Contested Landscape*, in *GLOBAL HEALTH GOVERNANCE*, *supra* note 17, at 27, 38 (noting “security” as one of the four competing perspectives—in addition to biomedicine, economism, and human rights). See generally McInnes, *supra* note 17 (discussing the relationship between global health governance and national security).

280. See generally QUAMMEN, *supra* note 140, at 385–489 (tracing the origin of HIV to zoonotic spillover from primates in Africa).

281. LISK, *supra* note 17, at 12.

282. See HOW A GLOBAL EPIDEMIC WAS STOPPED, *supra* note 27, at 226 (noting the “compelling evidence to suggest that the virus originated in animals [such as Himalayan palm civets, raccoon dogs, and Chinese ferret badgers] and then possibly mutated, becoming more readily transmissible between humans”).

283. WHO, *THE WORLD HEALTH REPORT 2007: A SAFER FUTURE: GLOBAL PUBLIC HEALTH SECURITY IN THE 21ST CENTURY* x (2007).

issue, thereby enabling it to attract attention it otherwise would not receive.<sup>284</sup> It would also help intellectual property negotiators realign their focus—not only with trade benefits, but also with greater security benefits within the global health system. Such a focus, in turn, would change their cost-benefit analyses. After all, “[i]nfectious disease accounts for around 26 per cent of all deaths worldwide and is one of the prime examples of a globalised issue requiring global response.”<sup>285</sup> With the many economic, demographic, and technological changes globalization has wrought, some experts also estimated that “a new influenza pandemic could kill up to 150 million people.”<sup>286</sup>

In recent years, rights holders, industry groups, and policymakers have actively sought to link intellectual property protection and enforcement to the security debate.<sup>287</sup> By linking piracy and counterfeiting to terrorism and organized crime,<sup>288</sup> they were able to obtain rhetorical advantage to push for new and higher standards of intellectual property protection and enforcement. Such framing efforts, however, deserve close scrutiny. As this section has shown, the security gains from strengthening intellectual property protection and enforcement standards do not always offset the security risks posed by overprotection of intellectual property rights in the less developed world to the global health arena. If a new integrated approach were adopted, it would question the largely one-sided analysis of security gains provided by high intellectual property standards.

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284. Cf. KELLEY LEE, *GLOBALIZATION AND HEALTH: AN INTRODUCTION* 18 (2003) [hereinafter LEE, *GLOBALIZATION AND HEALTH*] (“Th[e] wedding of the emerging global health agenda with realist-based notions of national security has resulted in the elevation of some health issues to ‘high’ politics. Since the late 1980s global health issues have received increasing attention within high-level policy circles, particularly in the United States.” (footnote omitted)).

285. Simon Rushton, *Global Governance Capacities in Health: WHO and Infectious Diseases*, in *GLOBAL HEALTH GOVERNANCE*, *supra* note 17, at 60, 60 (citation omitted).

286. *Id.*

287. See Susan K. Sell, *The Global IP Upward Ratchet, Anti-Counterfeiting and Piracy Enforcement Efforts: The State of Play* 3 (Program on Information Justice and Intellectual Property, American University Washington College of Law, Research Paper No. 15, 2010), available at

<http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1016&context=research> (“Introducing a security frame for [intellectual property] has allowed these [intellectual property] maximalists to enlist new actors, law enforcement agencies, in their cause. Law enforcement agencies have become eager recruits to the [intellectual property] maximalists’ network.”); see also Yu, *Two Development Agendas*, *supra* note 92, at 569 (“The use of this new rhetorical frame plays unfortunately to the widespread sentiments developed in the wake of the September 11 tragedies. Government officials, for example, have repeatedly described how terrorists have used piracy and counterfeiting to fund their operations.”).

288. For discussions linking piracy and counterfeiting to terrorism and organized crimes, see sources cited in Yu, *Enforcement, Enforcement*, *supra* note 234, at 246 n.26.

## 2. Lesson #2: The Radical Turn in Intellectual Property

The second set of gains developed countries could obtain is the prevention of a radical turn in intellectual property law and policy. The three virostories discussed in this Article not only demonstrate the less developed countries' ability to come up with different policy responses to address concerns and challenges in the public health arena, but also reveal an increasingly radical turn in intellectual property law and policy. Out of all three stories, the last story reflects the most radical approach to addressing deficiencies in the international patent system. While brand name pharmaceutical companies and their supportive developed country governments detest the less developed countries' use of compulsory licenses to provide downward adjustment of international patent standards, the radical approach taken by Indonesia, India, and other NAM members based on claims of "viral sovereignty" could inflict significant harm to intellectual property rights holders and their supportive governments.

To some extent, the push for recognition of viral sovereignty reminds us of the other radical turns in the history of the international patent system. For example, during the eighteenth century, many European countries, including Bismarck Germany, subscribed to the anti-patent movement.<sup>289</sup> Had Germany not changed course to support the international patent system,<sup>290</sup> the development of the Paris Convention for the Protection of Industrial Property ("Paris Convention")<sup>291</sup> would have been quite different. Even with the establishment of the Convention, countries such as the Netherlands and Switzerland continued to decline to offer patent protection.<sup>292</sup> It was indeed intriguing that these countries were allowed to

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289. See Peter K. Yu, *Currents and Crosscurrents in the International Intellectual Property Regime*, 38 LOY. L.A. L. REV. 323, 349 (2004). For discussions of the anti-patent movement, see generally Heinrich Kronstein & Irene Till, *A Reevaluation of the International Patent Convention*, 12 LAW & CONTEMP. PROBS. 765 (1947); Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. ECON. HIST. 1 (1950).

290. "The development of German patent legislation, jurisprudence and practice in the late nineteenth century was very much driven by newly-organised stakeholder groups and an emergent wider patent community." DUTFIELD, *supra* note 128, at 67. Nevertheless, "[w]ithin German industry as a whole there were a number of conflicting views. While the Society of German Engineers lobbied in favour of a patent law, there were still differences about the kind of patent law needed. . . . The chemical industry was also divided." *Id.* at 68.

291. Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 828 U.N.T.S. 305.

292. Although the Netherlands enacted patent law in 1817, it repealed the law in 1869. Machlup & Penrose, *supra* note 289, at 3, 5. For a discussion of the Netherlands and Switzerland during the time when they did not have a patent system while nearly all other industrialized countries had such a system in place, see generally ERIC SCHIFF, *INDUSTRIALIZATION WITHOUT NATIONAL PATENTS: THE NETHERLANDS, 1869-1912, SWITZERLAND, 1850-1907* (1971).

join the Paris Convention despite not offering any protection in the patent area.<sup>293</sup>

When many newly independent countries joined the international family of countries shortly after the Second World War, they quickly became dissatisfied with the international patent system, which was virtually imposed upon them by their former colonial masters.<sup>294</sup> Such dissatisfaction, in turn, led to major adjustments within both the domestic and international patent systems.

Consider India, for example. Shortly after gaining independence in 1947, the country established the Patents Enquiry Committee (Tek Chand Committee) to review the adequacy of the Indian patent system in promoting industrialization.<sup>295</sup> Finding that the extant system “enabled multinational companies to gain patent rights beyond the scope of their inventions,” the Committee “recommended incorporating compulsory licensing provisions to minimize the potential for abuse of monopolies.”<sup>296</sup> Its recommendations were subsequently incorporated into the patent law in 1950.

A decade later, the Indian government appointed Justice Rajagopala Ayyangar to head a committee that sought “to promote law reforms to improve local industrialization in critical areas like food and drugs.”<sup>297</sup> Taking into account the limited economic development within the country, the Ayyangar Committee unsurprisingly articulated the need for differential treatment for foodstuffs, medicines, chemical inventions, and educational materials; the prohibition of product patents (as opposed to process patents) in pharmaceuticals and agricultural chemicals; the provision of compulsory

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293. Eventually, Switzerland introduced patent protection in 1888, and the Netherlands followed suit in 1910. Before these countries introduced patent protection, both countries did have trademark laws in place. Such protection might have justified their Paris Convention memberships. SCHIFF, *supra* note 292, at 22. It is worth noting that the United States was able to join the Paris Union without offering any protection to utility models and with only limited protection to industrial designs. Pamela Samuelson, *Challenges for the World Intellectual Property Organisation and the Trade-Related Aspects of Intellectual Property Rights Council in Regulating Intellectual Property Rights in the Information Age*, 21 EUR. INTELL. PROP. REV. 578, 579 (1999).

294. See Ruth L. Okediji, *The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System*, 7 SING. J. INT'L & COMP. L. 315, 325–34 (2003) (providing an excellent discussion of how the former colonies conducted their international intellectual property relations following their declarations of independence).

295. See Srividhya Ragavan, *Of the Inequals of the Uruguay Round*, 10 MARQ. INTELL. PROP. L. REV. 273, 279 (2006).

296. *Id.*

297. *Id.* at 281.

licensing; and the local working requirement.<sup>298</sup> This report eventually paved the way for the establishment of the 1970 Patent Act, under which India did not provide patent protection for pharmaceutical products.<sup>299</sup> To a large extent, the very different regime India had until the expiry of the TRIPS transition period for pharmaceutical protections in 2005 has paved the way for the development of the Indian generic pharmaceutical industry.<sup>300</sup>

Like India, Brazil's developments have been rather important for the less developed world. In November 1961, "Brazil and many other developing nations demanded for the first time—within the UN system—rules on the protection of intellectual property . . . favourable to their economic development, including proper controls against abuse, thereby putting 'development' issues and 'public interest concerns' on the international [intellectual property] agenda."<sup>301</sup> Titled *The Role of Patents in the Transfer of Technology to Under-developed Countries*, this proposal was advanced against a background of dissatisfaction of the international patent system in Brazil.<sup>302</sup>

A few months earlier, the Brazilian Parliament established the Comissão Parlamentar de Inquerito (a special inquiry commission) "to analyze the domestic abuses of patent monopolies by multinational pharmaceutical corporations. The Commission made reference to the abuses regarding the non-working of patents by foreigners, the restrictive practices in licensing agreements, the payment of high royalties, including royalties for expired patents, and the high cost of medicines."<sup>303</sup> Although many developed countries considered Brazil's proposal "a threat to existing international conventions on patents and also to the hitherto unchallenged position of the Paris Union,"<sup>304</sup> the U.N. General Assembly eventually "passed a resolution

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298. See *id.* at 281–89 (discussing the Ayyangar Committee Report).

299. See Yu, *The International Enclosure Movement*, *supra* note 14, at 863.

300. See generally CHAUDHURI, *supra* note 14, at 180–221 (discussing the Indian generic pharmaceutical industry).

301. Andréa Koury Menescal, *Changing WIPO's Ways? The 2004 Development Agenda in Historical Perspective*, 8 J. WORLD INTELL. PROP. 761, 761–62 (2005).

302. See *id.* at 765.

303. *Id.* at 764.

304. As Ulf Anderfelt explained:

The criticism of [Brazil's proposal], as voiced by several delegations, emphasized three things: that abuses to which the patent system might give rise ought to be remedied through national legislation; that the existing machinery of the Paris Union was highly sufficient to deal with any questions concerning its field of activity and that countries not yet members ought to accede to it; and that particularly for developing countries unpatented or unpatentable technology was of greater importance than patented inventions.



requesting that the Secretary General prepare a report on the effects of patents on the economies of underdeveloped countries.”<sup>305</sup>

Even in the United States, major backlashes against the patent system existed in the late 1950s and early 1960s. As Graham Dutfield recounted:

From 1959 to 1962, the Senate Subcommittee on Antitrust and Monopoly, under the chairmanship of Senator Estes Kefauver, carried out an inquiry into the pharmaceutical industry. After three years of hearings, the Subcommittee concluded that the drug companies were charging too much for their drugs and making excessive profits. Through patenting and branding, Kefauver and the subcommittee believed, they were free to charge as much as they liked, and were using this freedom to excess.<sup>306</sup>

The timing of Senator Kefauver’s hearings was interesting because it coincided with extensive media reports about child birth defects caused by the use of thalidomide, a drug that had been heavily marketed to pregnant women at the time.<sup>307</sup> Following these hearings, Congress enacted the Kefauver-Harris Drug Amendments to introduce efficacy as a requirement for drug approval before the U.S. Food and Drug Administration.<sup>308</sup>

Understanding all these rather radical historical developments is important because such developments could easily reappear in the international patent system had developed countries not paid attention to the frustrations and concerns of less developed countries. Even worse, dissatisfaction with the current international intellectual property system can spread the same way and at the same speed as a contagious virus. Indeed, one may fear that, if developed countries continue to fail to meet the needs, interests, goals, and priorities of less developed countries, such failure could lead to a radical turn in the international patent system. It is also worth noting that the potential for such a turn would provide an

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ULF ANDERFELT, *INTERNATIONAL PATENT-LEGISLATION AND DEVELOPING COUNTRIES* 173 (1971).

305. Pedro Roffe & Gina Vea, *The WIPO Development Agenda in an Historical and Political Context*, in *THE DEVELOPMENT AGENDA: GLOBAL INTELLECTUAL PROPERTY AND DEVELOPING COUNTRIES* 79, 95 (Neil Weinstock Netanel ed., 2008) [hereinafter *THE DEVELOPMENT AGENDA*]. The resolution was reprinted in *Principal Decisions by the International Community Regarding the Patent System*, *WORLD DEV.*, Sept. 1974, at 37, 37.

306. DUTFIELD, *supra* note 128, at 148; *see also* ‘T HOEN, *supra* note 63, at 15 (“[Senator Kefauver’s] Subcommittee examined the price differences between US companies and foreign companies for a number of medicines widely-used at the time, including: tranquillisers, diabetes drugs, arthritis drugs and antibiotics. It also looked into marketing and advertising practices and the safety of medicines.”).

307. *See* Wallace F. Janssen, *Outline of the History of U.S. Drug Regulation and Labeling*, 36 *FOOD DRUG COSM. L.J.* 420, 437–41 (1981) (discussing “the lesson of thalidomide”).

308. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962).

important international context against which we analyze the growing number of patent decisions from the United States Supreme Court.

Nevertheless, for those less developed countries that seek to use radical approaches to increase their bargaining leverage, they should also be aware that radical approaches could backfire sometimes. While commentators, NGOs, and the public at large have sympathized with the positions on biopiracy taken by less developed countries, they have less sympathy for positions involving claims of viral sovereignty in the public health arena. If countries seek to deploy measures that are as radical as, or even more radical than, claims of viral sovereignty, such approaches could eventually undercut the considerable momentum less developed countries have built so far in their painstaking effort to recalibrate the balance in the international intellectual property system. If this scenario occurs, the push for a radical turn in intellectual property law and policy could hurt those countries that are in most need of such recalibration.

### *C. The Negotiation Process*

#### **1. Lesson #3: Growing Complexity and Fragmentation**

The global governance system is currently encountering two sets of major changes. In the past couple of decades, this system has become increasingly complex and fragmentary. As a result, the state-driven policy discussions have often implicated quite a number of disparate international regimes. In addition, the system has seen the increasing assertiveness of non-state actors. It is also confronted with the arrival of more powerful players, such as the BRICS countries (Brazil, Russia, India, China, and South Africa) and members of the African Group. This section will focus on the change in relation to the growing complexity and fragmentation within the international regulatory system, while the next two sections will focus on changes in relation to changing global governance.

Consider global HIV/AIDS governance for example. Although intellectual property issues concerning HIV/AIDS treatments are traditionally governed by conventions developed by WIPO and its predecessors, the establishment of the WTO and its TRIPS Agreement has steered the discussions toward the international trade arena. Intellectual property and trade, however, are not the only two fora in which intellectual property issues are being discussed. For instance, issues lying at the intersection of HIV/AIDS governance and intellectual property protection

have now been explored in the human rights forum.<sup>309</sup> Since the TRIPS Agreement entered into force, a number of U.N. human rights bodies—including the Sub-Commission on the Promotion and Protection of Human Rights, the High Commissioner for Human Rights, and two Special Rapporteurs on the Right to Health—have issued reports and documents emphasizing the primacy of human rights over the TRIPS Agreement and other international trade, intellectual property, and investment instruments.<sup>310</sup>

In addition, intellectual property issues concerning HIV/AIDS treatments have been closely scrutinized in the public health arena. In February 2004, the World Health Assembly established the Commission on Intellectual Property Rights, Innovation and Public Health.<sup>311</sup> The Commission's final report reminded us of the many adverse spillover effects of strong protection for pharmaceutical patents and undisclosed clinical trial data. The report eventually led to the May 2008 adoption of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property,<sup>312</sup> which sought to facilitate the development of funding and incentive mechanisms for the creation of new medicines.<sup>313</sup>

In light of the growing complexity and proliferation of fora that can be used to discuss global health governance issues, policymakers should think more about the discussion of intellectual property issues outside WIPO and the WTO. They should be more conscious of the potential conflict created by other international obligations, such as in the human rights or public health arena. In fact, commentators have increasingly embraced the protection of human rights as part of the needed rhetorical and normative bases for enhancing access to affordable HIV/AIDS treatments.<sup>314</sup> Although

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309. See Yu, *Two Development Agendas*, *supra* note 92, at 522–27.

310. See Intellectual Property Rights and Human Rights, Sub-Comm'n on Human Rights Res. 2000/7, ¶¶ 2–3, U.N. Doc. E/CN.4/Sub.2/RES/2000/7 (Aug. 17, 2000), available at <http://www.unhcr.ch/Huridocda/Huridoca.nsf/0/c462b62cf8a07b13c12569700046704e> (reminding governments “of the primacy of human rights obligations over economic policies and agreements” and the importance of other human rights, such as the right to food and the right to health); Peter K. Yu, *Reconceptualizing Intellectual Property Interests in a Human Rights Framework*, 40 U.C. DAVIS L. REV. 1039, 1092–93 (2007) [hereinafter Yu, *Reconceptualizing Intellectual Property Interests*] (discussing the principle of human rights primacy).

311. See Intellectual Property Rights, Innovation and Public Health, World Health Assembly Res. WHA56.27, ¶ 2(2) (May 28, 2003), available at [http://apps.who.int/gb/archive/pdf\\_files/WHA56/ea56r27.pdf](http://apps.who.int/gb/archive/pdf_files/WHA56/ea56r27.pdf).

312. Global Strategy and Plan of Action, *supra* note 107.

313. See ‘T HOEN, *supra* note 63, at 92–93.

314. See, e.g., Obijiofor Aginam, *Communitarian Globalism and Disease: A Normative Orientation for Global Health Governance*, in GLOBAL GOVERNANCE OF HIV/AIDS, *supra* note 16, at 14, 19–21 (discussing the “human rights versus intellectual property rights” debate);

existing international human rights agreements protect both the right to life and the right to health on the one hand and the human rights interests in intellectual creations on the other,<sup>315</sup> there is no denying that the right to life has now become part of customary international law.<sup>316</sup> The right to health has also been incorporated into strategies for reshaping the global health governance debate.<sup>317</sup>

In addition to thinking about strategies, policymakers should also be cognizant of the growing fragmentation of the international regulatory system. They need to think about how such fragmentation could have different impacts on countries based on their economic and technological conditions.

On the one hand, fragmentation will allow less developed countries to better protect their interests by mobilizing in favorable fora, laying down the needed political and diplomatic groundwork, and establishing new “counter-regime norms” that help restore the balance of the international intellectual property system.<sup>318</sup> The existence of multiple fora will also help promote “norm competition across different fora as well as . . . inter-agency

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James Harrison, *Trade Agreements, Intellectual Property and Access to Essential Medicines: What Future Role for the Right to Health?*, in GLOBAL GOVERNANCE OF HIV/AIDS, *supra* note 16, at 87 (discussing the role of right to health in HIV/AIDS governance); Carlos Correa & Duncan Matthews, *The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to Health* (U.N. Dev. Programme, Discussion Paper, 2011), available at <http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/doha10yearson.html> (discussing the impact of the Doha Declaration on access to medicines and the right to health).

315. For the Author’s earlier discussions of the human rights interests in intellectual creations, see generally Peter K. Yu, *Intellectual Property and Human Rights in the Nonmultilateral Era*, 64 FLA. L. REV. 1045 (2012) [hereinafter Yu, *Intellectual Property and Human Rights*]; Yu, *Reconceptualizing Intellectual Property Interests*, *supra* note 310; Peter K. Yu, *Ten Common Questions About Intellectual Property and Human Rights*, 23 GA. ST. U. L. REV. 709 (2007).

316. For discussions of customary international law status of protections under the Universal Declaration of Human Rights, including the right to life and right to health, see sources cited in Yu, *Intellectual Property and Human Rights*, *supra* note 315, at 1065 n.93.

317. See generally HESTERMEYER, *supra* note 14 (discussing the right to health in relation to the intellectual property debate).

318. See Donald J. Puchala & Raymond F. Hopkins, *International Regimes: Lessons from Inductive Analysis*, in INTERNATIONAL REGIMES 66 (Stephen D. Krasner ed., 1983) (defining “counterregime norms” as norms that “either circulate in the realm of rhetoric or lie dormant as long as those who dominate the existing regime preserve their power and their consequent ability to reward compliance and punish deviance”); Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT’L L. 1, 14 (2004) (defining “counter-regime norms” as “binding treaty rules and nonbinding soft law standards that seek to alter the prevailing legal landscape”).

competition and collaboration.”<sup>319</sup> As Kelly Lee reminded us, “[i]t was within th[e] context of institutional rivalry that the goal of polio eradication was agreed and pursued by the WHO, UNICEF and partner organizations (such as Rotary International and the CDC) at the World Summit for Children in 1990.”<sup>320</sup>

On the other hand, fragmentation could benefit developed countries by raising the transaction costs of policy negotiation and coordination, thereby helping these powerful countries to retain the status quo.<sup>321</sup> These higher costs, coupled with the increased incoherence and complexities in the international intellectual property system, are particularly damaging to less developed countries, which often lack resources, expertise, leadership, negotiation sophistication, and bargaining power. By forcing countries to prioritize, fragmentation also makes them vulnerable to the ever-increasing forum-manipulative activities undertaken by powerful developed countries,<sup>322</sup> including the development of bilateral, plurilateral, and regional TRIPS-plus trade and investment agreements.

## 2. Lesson #4: Changing Governance

From the Paris Convention to the TRIPS Agreement, the international intellectual property system was built upon a state-centric international legal system. This system “historically deferred to states as the guardians of domestic welfare, with the assumption that the appropriate exercise of sovereign power for domestic public interest would inure inevitably to the benefit of the global community.”<sup>323</sup> To the extent non-state actors are involved, their interests are usually reflected through those state actors representing them.<sup>324</sup> Before the establishment of the TRIPS Agreement, corporations and industry groups made up most of the nongovernmental participants in the international intellectual property norm-setting process.<sup>325</sup>

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319. P. BERNT HUGENHOLTZ & RUTH L. OKEDIJI, CONCEIVING AN INTERNATIONAL INSTRUMENT ON LIMITATIONS AND EXCEPTIONS TO COPYRIGHT: FINAL REPORT 41 (2008), available at <http://www.ivir.nl/publicaties/hughenoltz/finalreport2008.pdf>.

320. KELLEY LEE, THE WORLD HEALTH ORGANIZATION (WHO) 68 (2009).

321. See generally Eyal Benvenisti & George W. Downs, *The Empire's New Clothes: Political Economy and the Fragmentation of International Law*, 60 STAN. L. REV. 595 (2007) (discussing how the growing proliferation of international regulatory institutions with overlapping jurisdictions and ambiguous boundaries has helped powerful states to preserve their dominance in the international arena).

322. See *supra* text accompanying notes 249–50.

323. Okediji, *International Copyright System*, *supra* note 94, at ix.

324. See Yu, *Two Development Agendas*, *supra* note 92, at 547.

325. See *id.* at 548; see also Noah Benjamin Novogrodsky, *Beyond TRIPS: The Role of Non-state Actors and Access to Essential Medicines*, in INCENTIVES FOR GLOBAL PUBLIC

Since the adoption of the TRIPS Agreement, however, civil society organizations have become much more active in the intellectual property arena. Indeed, many NGOs found themselves “woken up” by the harsh realities the unbalanced TRIPS Agreement brought and the public health crises the Agreement precipitated in the less developed world.<sup>326</sup> In retrospect, Sisule Musungu and Graham Dutfield considered “[c]ivil society groups . . . the single most important factor in raising the issue of the impact of the international intellectual property standards, especially TRIPS standards, on development issues such as health, food and agriculture.”<sup>327</sup> Andrea Menescal also observed that “[t]he most welcome news to emerge from the 2004 [WIPO Development Agenda] debate is that developing countries’ governments are no longer alone in opposing an even further

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HEALTH, *supra* note 63, at 343, 345 (“In the beginning, most NGOs were conspicuously absent from the debates surrounding the creation of global intellectual property mechanisms.”).

326. See SELL, *supra* note 211, at 181 (“When I asked some public-regarding copyright activists ‘where they had been’ during TRIPS, they told me they had been ‘sleeping’ but that because of TRIPS they had ‘woken up.’”); Ellen ‘t Hoen, *The Revised Drug Strategy: Access to Essential Medicines, Intellectual Property, and the World Health Organization*, in ACCESS TO KNOWLEDGE IN THE AGE OF INTELLECTUAL PROPERTY 127, 131 (Gaëlle Krikorian & Amy Kapczynski eds., 2010) [hereinafter ACCESS TO KNOWLEDGE] (stating that it was at the International Conference on National Medicinal Drug Policies in Sydney in 1995 that “for the first time public-health advocates raised the concern that the globalization of new international trade rules and the harmonization of regulatory requirements would restrict countries’ ability to implement drug policies that would ensure access to medicine for all”); Keith E. Maskus, *The WIPO Development Agenda: A Cautionary Note*, in THE DEVELOPMENT AGENDA, *supra* note 305, at 163, 164 (“Policymakers, non-governmental organizations, the media, and even many legal scholars have awakened to the fact that [intellectual property] regulations have rather fundamental implications for the processes of economic development.”); see also Novogrodsky, *supra* note 325, at 356 (“NGOs operating in this space are part of a broad movement that has served to politicize the previously arcane field of intellectual property law. . . . NGOs at the forefront of the struggle for affordable and accessible medicines stand poised to force a reconception of allegiances, values and state-citizen relationships.”).

327. Sisule F. Musungu & Graham Dutfield, *Multilateral Agreements and a TRIPS-plus World: The World Intellectual Property Organisation (WIPO)* 22 (Quaker United Nations Office, TRIPS Issues Paper No. 3, 2003), available at <http://www.quno.org/sites/default/files/resources/Multilateral-Agreements-in-TRIPS-plus-English.pdf> (footnote omitted); see also DEERE, *supra* note 259, at 114 (“A key result of post-TRIPS tensions was the deepening complexity of the global [intellectual property] system. The range of non-state actors involved in global [intellectual property] debates became broader and many NGOs, industry groups, international organizations . . . and academic experts deepened their degree of engagement.”); SELL, *supra* note 211, at 140 (“[W]hat is new is the mobilization of [grassroots activists, farmers’ groups, environmental groups, development groups, human rights groups, and consumer groups] to oppose an increasingly aggressive approach to intellectual property by US corporations.”). For an excellent discussion of the role played by NGOs in the international intellectual property debate, see generally DUNCAN MATTHEWS, INTELLECTUAL PROPERTY, HUMAN RIGHTS AND DEVELOPMENT: THE ROLE OF NGOS AND SOCIAL MOVEMENTS (2011).

strengthening of the [intellectual property] holders' rights and the prevalence of private interests in the [intellectual property] field."<sup>328</sup>

In the public health arena, Noah Benjamin Novogrodsky further noted that "[s]ome NGOs, particularly MSF [Médecins Sans Frontières], the Consumer Project on Technology (now Knowledge Ecology International) and Health Action International played a significant role in the processes leading up to the adoption by WTO members of a declaration on TRIPS and Public Health at the Doha Conference on 14 November 2001."<sup>329</sup> In his view, these organizations "have revolutionized advocacy on the national and international stage, most dramatically with respect to antiretroviral drugs used to combat HIV/AIDS."<sup>330</sup>

In fact, the growing assertiveness of civil society organizations and the changing nature of the global governance model are not limited to the intellectual property field alone. They happen across the board in the international regulatory system. In the past few decades, that system has slowly transformed from a simple Westphalian nation-state model to a more pluralistic order featuring complex, transnational interactions among state governments, intergovernmental bodies, international donor organizations, sub-state and non-state actors, and the private sector.<sup>331</sup> As John Kirton and Andrew Cooper observed:

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328. Menescal, *supra* note 301, at 794.

329. Novogrodsky, *supra* note 325, at 350; *see also* MATTHEWS, *supra* note 327, at 15–51 (discussing the role played by health NGOs in the run-up to the adoption of the Doha Declaration and its aftermath).

330. Novogrodsky, *supra* note 325, at 343.

331. As Ilona Kickbusch observed:

[T]he traditional state-centric system of international politics both runs in parallel to and interfaces with a system of global governance which tries to bundle and coordinate lobbies, interest groups, policy networks, advocacy groups, alliances, partnerships, foundations, international organizations and states—all of which in turn come together in a different hybrid forms of organization. Additionally, the familiar processes of state-based multilateral governance are increasingly challenged both by market multilateralism, for example the World Economic Forum, and by 'charitainment' as personified by Bono. No longer do diplomats just talk to other diplomats—everyone talks to everyone else. Access to and legitimacy within this system are no longer gained through status as a nation-state but through a range of other mechanisms: expertise, moral standing and increasingly the demonstrated ability to achieve results.

Kickbusch, *supra* note 279, at xiv (citations omitted); *see* FIDLER, *supra* note 27, at 187–88 ("Although strategies for infectious disease control had already begun to move away from the Westphalian model, the handling of the SARS outbreak has taken this transition to a new level of importance and potential effectiveness that makes any return to Westphalian modes of surveillance unthinkable."); Bartsch et al., *supra* note 253, at 18–19 ("[Global health governance] must be seen as an ongoing process of institutional change. It is part of the

[S]tates are no longer always the dominant actors, as they are now joined as important innovators in key cases by sub-national actors below, transnational actors across their borders, and international actors above. In all cases a multiplicity of actors has become involved in shaping responses. Many arose as innovators or catalysts for innovation by others. Within states, civil society and often the media stand out as driving change and providing disease surveillance, delivery, implementation and overall legitimacy.<sup>332</sup>

Consider global HIV/AIDS governance again. From programs the WHO developed to the ongoing negotiations in the Doha Round, governments have worked closely to confront the HIV/AIDS crisis head-on. NGOs have also entered the fold to provide non-state based assistance, especially in areas where national governments alone could not achieve satisfactory outcomes. These NGOs include ACT UP!, Health Action International, the Health Global Access Project (Health GAP), the International Centre for Trade and Sustainable Development (ICTSD), Knowledge Ecology International, MSF, Oxfam, Public Citizen, the Third World Network, the Trade Law Centre for Southern Africa (tralac), and the Treatment Action Campaign.<sup>333</sup>

Apart from traditional NGOs, new private foundations, such as the Bill and Melinda Gates Foundation and the William J. Clinton Foundation, have also emerged from the non-state sector.<sup>334</sup> The substantial resources of the Gates Foundation have ushered in exciting initiatives in vaccine development and global health research. Although some commentators have

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transitional process from a Westphalian structure of international relations between sovereign nation-states to a post-Westphalian global political system.”); Peter K. Yu, *The Global Intellectual Property Order and Its Undetermined Future*, 1 WIPO J. 1, 2 (2009) [hereinafter Yu, *Global Intellectual Property Order*] (“[T]he traditional international legal order, which was built upon the Westphalian nation-state model, has now morphed into a more pluralistic order that includes a wide range of state, sub-state, and non-state actors.”).

332. Kirton & Cooper, *Innovation in Global Health Governance*, *supra* note 166, at 328; *see also* LEE, GLOBALIZATION AND HEALTH, *supra* note 284, at 202 (“Global health governance (GHG) . . . concerns cooperation among state and non-state actors to address issues of a transborder nature. While GHG is a nascent form of governance, important examples include the Framework Convention on Tobacco Control . . . and Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria.” (citation omitted)); Craig N. Murphy, *Foreword: Why Pay Attention to Global Governance?*, in GLOBAL GOVERNANCE, *supra* note 252, at xi–xii (“[A]s a consequence of neoliberal marketisation, the services once provided by public intergovernmental organisations are now contracted to private, non-governmental, often ‘social movement’-style, organisations. Today it is . . . NGOs who run the refugee camps, provide disaster relief, design and carry-out development projects, monitor and attempt to contain the international spread of disease, and try to clean up an ever more polluted environment.”).

333. Yu, *Access to Medicines*, *supra* note 67, at 377.

334. *See* SOPHIE HARMAN, THE WORLD BANK AND HIV/AIDS: SETTING A GLOBAL AGENDA 112–15 (2010) (discussing philanthropy and new forms of HIV/AIDS financing).



expressed reservation about the Foundation's focus on biomedical science, emphasis on intellectual property rights, and limited interest in infrastructural development,<sup>335</sup> most are thankful for the many opportunities created by this new player: The Foundation's war chest alone exceeds the public health budgets of many less developed countries.

To some extent, the participation of NGOs in providing expertise to the intellectual property debate has changed the dynamics of the discussions. Coined by Pat Mooney, the co-founder of Rural Advancement Foundation International (RAFI),<sup>336</sup> the term "biopiracy" has provided the needed rhetorical groundwork for later claims of "viropiracy" and "viral sovereignty." Turning the word "piracy" on its head,<sup>337</sup> the term biopiracy (and now viropiracy) brings with it the massive energy that industry groups and rights holders have built over the years—ironically, for stronger intellectual property rights. In sum, HIV/AIDS governance is global in every sense of the word.<sup>338</sup>

Given the increasing fragmentation within the international regulatory system and growing importance of non-state actors in this system, one has to think more about how international intellectual property negotiations should be conducted. ACTA provides a good but disturbing example. It illustrates both the complexity within the international intellectual property regime as well as the need for greater input from non-state actors. Thus far, ACTA has been one of the most heavily criticized international intellectual property negotiations conducted by the United States, Japan, members of the European Union, Switzerland, and other developed and like-minded countries. Among some of the major public interest concerns of ACTA were "(1) lack of transparency; (2) very limited public, non-industry

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335. For criticisms of the Gates Foundation, see *id.* at 114; Lee, *supra* note 279, at 27, 32; Matthew Rimmer, *The Lazarus Effect: The (RED) Campaign and Creative Capitalism*, in INCENTIVES FOR GLOBAL PUBLIC HEALTH 329–32 (Thomas Pogge et al. eds., 2010).

336. DUTFIELD, *supra* note 128, at 265. RAFI has now become the ETC Group.

337. See Yu, *Two Development Agendas*, *supra* note 92, at 571–72.

338. As Sonja Bartsch, Wolfgang Hein, and Lars Kohlmorgen observed:

The constellation of actors in the fight against HIV/AIDS—as in the field of global health governance in general—is very heterogeneous, with actors differing not only with regard to their character (public, non-public), their institutional structure (formalized, informal), or their level of activity (global, national, local), but also with regard to their interests, their logic of action and their power resources.

Bartsch et al., *supra* note 253, at 36. For collections of articles discussing how the global health governance has grown beyond the state-based model, see generally GOVERNANCE OF HIV/AIDS: MAKING PARTICIPATION AND ACCOUNTABILITY COUNT (Sophie Harman & Franklyn Lisk eds., 2009); FIGHT AGAINST HIV/AIDS, *supra* note 17.

participation; (3) a huge democratic deficit; and (4) virtually no domestic or global accountability.”<sup>339</sup>

As Robert Weissman of Essential Action noted in the comments on ACTA his organization submitted to the USTR: “There is no conceivable rationale for the cloak-and-dagger aura around the talks, and the refusal to disclose draft texts and relevant background documents.”<sup>340</sup> Likewise, Robin Gross of IP Justice lamented:

The lack of transparency and public participation in the process to negotiate ACTA is deeply troubling to anyone who cares about democracy and the public interest. Outside of a scant press release or two, the USTR has provided the general public with virtually no public information about the proposed substance of ACTA.<sup>341</sup>

Given the lack of transparency in the ACTA negotiations, it is indeed ironic—if not hypocritical—that the Agreement includes transparency provisions even when their negotiations were not transparent at all.<sup>342</sup> Also troubling are the negative impacts these negotiations will have on the developed countries’ ongoing effort to promote democracy and the rule of law in other parts of the world.<sup>343</sup>

To be certain, the negotiations would contain some classified or highly sensitive information from negotiating governments.<sup>344</sup> It is also not hard to see how the disclosure of all draft treaty texts could have complicated the dynamics of the negotiations. As I noted in a previous article:

[The United States’] concern was mainly due to the fear that such disclosure would result in parties walking away from the negotiation table (in addition to further complications in the ongoing negotiations of other trade and investment agreements). As far as the agreement’s impact on domestic politics is concerned, however, the US negotiators are likely to have much

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339. Yu, *Six Secret Fears*, *supra* note 234, at 998–99.

340. Letter from Robert Weissman, Dir., Essential Action, to Susan Schwab, U.S. Trade Representative (Sept. 17, 2008), available at [http://www.ustr.gov/sites/default/files/uploads/factsheets/2008/asset\\_upload\\_file989\\_15121.pdf](http://www.ustr.gov/sites/default/files/uploads/factsheets/2008/asset_upload_file989_15121.pdf).

341. Robin Gross, *ACTA’s Misguided Effort to Increase Govt Spying and Ratchet-Up IPR Enforcement at Public Expense*, IP JUST. (Mar. 21, 2008, 9:35 AM), <http://ipjustice.org/wp/2008/03/21/acta-ipj-comments-ustr-2008march/>.

342. See ACTA, *supra* note 30, art. 30.

343. See Yu, *Six Secret Fears*, *supra* note 234, at 1050–59 (discussing how ACTA may undermine the United States’ longstanding interests in promoting human rights, civil liberties, and the rule of law throughout the world).

344. See *id.* at 1002–08 (discussing the protection against classified or highly sensitive information during the ACTA negotiations).

less to worry about than their counterparts in emerging countries.<sup>345</sup>

Nevertheless, if the leakage of sensitive information from foreign governments and the changing dynamics of the negotiations are the main concerns, at the very least policymakers should frequently and adequately communicate to the public the contents of those agreements. They should also include ample opportunities for the public to provide feedback on these agreements, as opposed to only limited opportunities after the conclusion of the agreements.

To some extent, the need for transparency in intellectual property negotiations resonates well with the need for transparency in the global health arena—or, for that matter, the international regulatory system. As Holbrooke and Garrett emphatically noted in an opinion piece highly critical of Indonesia's viral sovereignty claims: "As the world learned with the emergence of . . . SARS . . . —which first appeared in China in 2002 but was not reported by Chinese officials until it spread to four other nations—globally shared health risk demands absolute global transparency."<sup>346</sup>

In sum, given the growing fragmentation in the international intellectual property system and the rapid emergence of non-state actors, the international intellectual property debate is likely to become more interesting and pluralistic. Because non-state actors bring to the table highly diverging interests, focuses, and mindsets, the ability to reach for compromise in patent reforms will also become more difficult. Nonetheless, if compromises are successfully struck, the inclusiveness of the norm-setting process could make these compromises more legitimate and long-lasting.<sup>347</sup>

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345. Yu, *ACTA and Its Complex Politics*, *supra* note 234, at 13; see also James Love, *Ambassador Kirk: People Would Be "Walking away from the Table" If the ACTA Text Is Made Public*, KNOWLEDGE ECOLOGY INT'L (Dec. 3, 2009, 5:31 PM), <http://keionline.org/node/706> (noting the USTR's concern).

346. Holbrooke & Garrett, *supra* note 181.

347. See Wolfgang Hein et al., *Conclusion: Global Health Governance and the Fight Against HIV/AIDS in a Post-Westphalian World*, in *FIGHT AGAINST HIV/AIDS*, *supra* note 17, at 226, 240 [hereinafter Hein et al., *Conclusion*] ("The rise of new institutional forms and many new actors in global politics creates a structure of global governance that is more inclusive than the one based only on state regulation."). A point of comparison is the ACTA negotiations, where the exact reverse happened. See Yu, *Six Secret Fears*, *supra* note 234, at 1015 ("[I]f ACTA ultimately is to be accepted by the public as fair and legitimate, completing the agreement through a shady backdoor deal is unlikely to lead to wide public acceptance of the new norms embodied in the agreement."); Kimberlee Weatherall, *The Anti-Counterfeiting Trade Agreement: What's It All About?* (unpublished manuscript), available at <http://works.bepress.com/cgi/viewcontent.cgi?article=1017&context=kimweatherall> (last visited Oct. 30, 2013) ("The secrecy is . . . operating, once again, to bring intellectual property law into

### 3. Lesson #5: Emerging Players

Whether the debate is about access to essential medicines or the protection of genetic materials in viruses, less developed countries have played a very important role. Of particular importance are the policy positions taken by leaders of this group: Brazil, China, and India. It is no coincidence that these countries are frequently mentioned in all three virostories. Indeed, commentators have paid increasing attention to the development of the so-called BRICS countries, which originally included only Brazil, Russia, India, and China but has since been slowly extended to cover South Africa and other large developing countries.<sup>348</sup>

The importance of Brazil, China, and India in the global health debate does not need much explanation. Featuring companies such as Cipla, Dr. Reddy's Laboratories, and Ranbaxy, the Indian generic pharmaceutical industry is considered one of the most important and sophisticated in the world.<sup>349</sup> Because India "makes more than a fifth of the world's generic drugs"<sup>350</sup> and eighty-five percent of generic HIV/AIDS antiretrovirals in Sub-Saharan Africa,<sup>351</sup> commentators have noted the significant impact a reduced supply of Indian generic drugs would have on the global access to essential medicines in the less developed world.<sup>352</sup>

Like India, Brazil plays a very important role in the public health debate. Brazil is the poster child of the use of—or, more precisely, the threat to use—compulsory licenses to promote access to essential medicines.<sup>353</sup> Although the country has repeatedly obtained concessions from brand name pharmaceutical companies through these threats, it finally granted

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disrepute. To the extent that at some later point governments and [intellectual property] owners will ask people to accept the outcomes as 'fair' and ones that should be adopted, it will be more difficult to convince them when the agreement has the appearance of a secret deal done with minimal public input.").

348. See, e.g., CHIDI OGUAMANAM, *INTELLECTUAL PROPERTY IN GLOBAL GOVERNANCE: A DEVELOPMENT QUESTION* 221–22 (2012) (expanding BRICS to cover other emerging middle-income economies); Yu, *Access to Medicines*, *supra* note 67, at 346 (expanding the BRICS acronym to cover South Africa); Sébastien Hervieu, *South Africa Gains Entry to BRIC Club*, *GUARDIAN WKLY.* (Apr. 19, 2011, 9:04 AM), <http://www.guardian.co.uk/world/2011/apr/19/south-africa-joins-bric-club> (reporting that the South African president joined his counterparts from Brazil, Russia, India, and China for the third summit of the informal group in China).

349. See generally CHAUDHURI, *supra* note 14, at 180–221 (discussing the growth and prospects of generic drug exports from India).

350. KAMAL NATH, *INDIA'S CENTURY* 110 (2008).

351. See Colleen Chien, *HIV/AIDS Drugs for Sub-Saharan Africa: How Do Brand and Generic Supply Compare?*, 2 *PLOS ONE* e278 (2007); see also Shadlen, *Is AIDS Treatment Sustainable?*, *supra* note 102, at 36 ("It is estimated that more than half of those receiving AIDS treatment in the developing world are treated with generic [antiretrovirals] produced in India.").

352. See *supra* text accompanying notes 102–03.

353. See *supra* text accompanying notes 64–70.

compulsory licenses for the noncommercial public use of the patented AIDS drug efavirenz in April 2007.<sup>354</sup> It remains to be seen how active Brazil will be in using compulsory licenses to promote public health.

In the mid-1980s, Brazil launched its now very successful National STD/AIDS Programme, which provides free, universal access to HIV/AIDS treatments. This program has been widely recognized as a model for the less developed world.<sup>355</sup> As the IPR Commission documented in its final report, the National STD/AIDS Programme “has reduced AIDS-related mortality by more than 50 percent between 1996 and 1999. In two years, Brazil saved \$472 million in hospital costs and treatment costs for AIDS-related infections.”<sup>356</sup>

China is the late comer in this trio, but it has since moved up very quickly. As I noted in an earlier article, “[a]lthough China has yet to be as aggressive as India in exporting drugs or as successful as Brazil in promoting public health within the country, it already is the world’s largest producer of active pharmaceutical ingredients and is likely to be a very important player in the generic market.”<sup>357</sup> In addition, “China has advantages in producing ‘me too’ drugs because its capacity to conduct organic synthesis is very strong after many years of China’s being the target for outsourced [multinational pharmaceutical companies’] business.”<sup>358</sup>

It is also worth noting that Margaret Chan, a Chinese national, is now serving her second term as the WHO Director-General.<sup>359</sup> As one commentator observed:

The election of Margaret Chan as the director general of the WHO in 2006 has shown that China is not complacent about merely acting as a passive follower of liberal international order and is

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354. Press Release, Brazilian Ministry of Health, Brasil decreta licenciamento compulsorio do Efavirenz (May 4, 2007), *available at* <http://www.aids.gov.br/noticia/brasil-decreta-licenciamento-compulsorio-do-efavirenz>.

355. See IPR COMMISSION REPORT, *supra* note 29, at 43 (noting that the National STD/AIDS Programme in Brazil “has been widely acclaimed as a possible model for other countries”); John S. Odell & Susan K. Sell, *Reframing the Issue: The WTO Coalition on Intellectual Property and Public Health, 2001*, in NEGOTIATING TRADE: DEVELOPING COUNTRIES IN THE WTO AND NAFTA 85, 96 (John S. Odell ed., 2006) (“Developing countries looked to Brazil as a beacon of hope in strategies to combat the HIV/AIDS crisis.”); ‘t Hoen, *TRIPS, Pharmaceutical Patents*, *supra* note 64, at 32 (noting that “[t]he Brazil AIDS program serves as a model for some developing countries that are able to produce medicines locally”).

356. ‘t Hoen, *TRIPS, Pharmaceutical Patents*, *supra* note 64, at 32.

357. Yu, *Access to Medicines*, *supra* note 67, at 363.

358. LI YAHONG, IMITATION TO INNOVATION IN CHINA: THE ROLE OF PATENTS IN BIOTECHNOLOGY AND PHARMACEUTICAL INDUSTRIES 54 (2010).

359. Press Release, WHO, Dr Margaret Chan Appointed to a Second Term as Director-General, (May 23, 2012), *available at* [http://www.who.int/mediacentre/news/releases/2012/dg\\_appointment\\_20120523/en/](http://www.who.int/mediacentre/news/releases/2012/dg_appointment_20120523/en/).

striving for a greater say in global health governance. . . . It has been widely believed that China's success was largely due to Beijing's blessing and her appointment was seen as a diplomatic triumph for her and for China.<sup>360</sup>

To illustrate the growing importance of the BRICS countries in the global health debate, consider their increasingly assertive roles in the WHO:

During the World Health Assembly of May 2004, Brazil, South Africa, China, India, Nigeria, Russia, Thailand and Ukraine committed themselves to establishing a network of technological cooperation on AIDS, with the financial support of the Ford Foundation, to reduce the technological dependency of developing countries compared to developed countries, to promote new drug producers on the world market and to catalyse antiretroviral price reductions. And during the fifteenth International Conference on AIDS held in Bangkok in July 2004, these countries (except for India and South Africa) signed a joint declaration of commitment. The technological network of cooperation on AIDS was officially created between Argentina, Brazil, China, Cuba, Nigeria, Russia, Thailand and Ukraine during the fifty-eighth World Health Assembly of 17 May 2005. The aim is to allow countries located in the most affected areas to increase their local output of generic drugs and various tests by exchanging their technologies: condoms for Thailand, generic drugs and diagnostic tests for Brazil, production of raw materials for China, diagnostic tests for Russia and so on. The network also aims to develop joint research to partially copy new antiretroviral drugs.<sup>361</sup>

The BRICS countries have also become more assertive in the WTO. At the June 2010 TRIPS Council meeting, both China and India made important interventions expressing concerns about the inappropriate push for TRIPS-plus enforcement norms through the highly controversial ACTA and other bilateral and regional trade agreements.<sup>362</sup> A month earlier, India and Brazil filed complaints with the WTO Dispute Settlement Body against the European Union and the Netherlands over the seizure of in-transit generic drugs.<sup>363</sup>

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360. CHAN LAI-HA, CHINA ENGAGES GLOBAL HEALTH GOVERNANCE: RESPONSIBLE STAKEHOLDER OR SYSTEM-TRANSFORMER? 213–14 (2011).

361. Amélie Robine, *Technology Transfer Agreements and Access to HIV/AIDS Drugs: The Brazilian Case*, in POLITICAL ECONOMY OF HIV/AIDS, *supra* note 16.

362. See TRIPS Council, Minutes of Meeting ¶¶ 248–73, IP/C/M/63 (Oct. 4, 2010); see also Yu, *TRIPS and Its Achilles' Heel*, *supra* note 57, at 518–21 (discussing these interventions).

363. See sources cited *supra* note 105.

Another group that has been actively emerging in the public health arena is the African Group.<sup>364</sup> In the debate leading up to the adoption of Article 31*bis* of the TRIPS Agreement, members of this Group advanced proposals with clearly defined positions.<sup>365</sup> Their active participation eventually led to compromises that took serious consideration of its needs, interests, conditions, and priorities. The successful adoption of the Doha Declaration can also be attributed to the active engagement of Zimbabwe,<sup>366</sup> whose delegate served as the chair of the TRIPS Council at that time.<sup>367</sup>

Outside the public health arena, the African Group has also joined the major developing countries in advancing proposals to reform the international intellectual property system. For instance, in July 2006, Tanzania cosponsored the proposal for the introduction of a new Article 29*bis* into the TRIPS Agreement.<sup>368</sup> That provision would create an obligation to disclose in patent applications the source of origin of the biological resources and traditional knowledge used in patent-seeking inventions.<sup>369</sup>

Disturbingly, despite the growing importance of both the BRICS countries and the African Group in the global health debate, members of neither groups had been invited to negotiate new and higher intellectual property protection and enforcement standards in ACTA or the TPP. To some extent, these two plurilateral agreements were set up as “country club”

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364. See DEERE, *supra* note 259, at 123.

365. See African Group Proposal, *supra* note 42 (providing the proposal for the African Group); Communication from Kenya, *Elements of a Paragraph 6 Solution*, IP/C/W/389 (Nov. 14, 2002) (advancing the position on behalf of the African Group); see also Yu, *The International Enclosure Movement*, *supra* note 14, at 879–81 (discussing the position of the African Group in relation to the Paragraph 6 solution).

366. See Sangeeta Shashikant, *The Doha Declaration on TRIPS and Public Health: An Impetus for Access to Medicines*, in ACCESS TO KNOWLEDGE, *supra* note 326, at 141, 146 (“Zimbabwe, on behalf of the Africa Group, proposed that the Doha Ministerial Conference to be convened later in the same year issue a special declaration to affirm a common understanding that the TRIPS Agreement does not prevent members from taking measures to protect public health . . .”).

367. Zimbabwean Ambassador Boniface Chidyausiku chaired the TRIPS Council in its formal meeting on June 18–22, 2001. WTO, ANNUAL REPORT (2001) OF THE COUNCIL FOR TRIPS (2001). He also “requested a special TRIPS Council session on access to medicines.” Susan K. Sell, *TRIPS and the Access to Medicines Campaign*, 20 WIS. INT’L L.J. 481, 512 (2002).

368. See Communication from Brazil, China, Colombia, Cuba, India, Pakistan, Peru, Thailand and Tanzania, *Doha Work Programme—The Outstanding Implementation Issue on the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity*, WT/GC/W/564/Rev.2 (July 5, 2006).

369. See *id.* ¶ 2 (requiring patent applicants to “disclose the country providing the resources and/or associated traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin”).

agreements,<sup>370</sup> whose key strategy was to isolate the emerging players to ensure more effective negotiated outcomes.<sup>371</sup> Nevertheless, if these countries are important to global health governance and have gained economic and geopolitical importance in recent years, it is worth thinking about whether such an exclusion strategy would eventually make the new initiatives ineffective.

After all, considering the growing importance of global health problems, country club-based solutions that are developed out of key developed and like-minded countries are unlikely to be successful. This would be true regardless of whether the issues concern patented pharmaceuticals or counterfeit drugs. As of this writing, China and other BRICS countries remain the major sources of counterfeiting in the world.<sup>372</sup> Greater collaboration between these countries and their counterparts in the developed world are therefore unavoidable.

Moreover, as Fareed Zakaria rightly reminded us in his discussion of the Western leaders chosen for the International Monetary Fund and the World Bank, “customs of an old segregated country club . . . may be charming and amusing to insiders, but to outsiders it is bigoted and outrageous.”<sup>373</sup> At a time when international cooperation is greatly needed in the public health arena, the resentment created by the country club-approach to international norm-setting is likely to be highly counter-productive.

Even worse, as noted in Part IV.A, communicable diseases have presented a much more complicated picture. Whatever happens in the BRICS countries could easily affect those in the developed world. As Obijiofor Aginam rightly observed:

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370. As Daniel Gervais explained, “I refer to this approach as ‘Country Club’ because, like a country club, the membership rules are negotiated by a number of like-minded founders. Others are then invited to join, but changes to the membership rules are difficult to achieve.” Daniel Gervais, *Country Clubs, Empiricism, Blogs and Innovation: The Future of International Intellectual Property Norm Making in the Wake of ACTA*, in *TRADE GOVERNANCE IN THE DIGITAL AGE* 323, 324 (Mira Burri & Thomas Cottier eds., 2012).

371. For criticisms of the ill-advised “country club” approach to international norm-setting, see generally Yu, *ACTA and Its Complex Politics*, *supra* note 234, at 5–9; Yu, *Six Secret Fears*, *supra* note 234, at 1074–83.

372. For the Author’s earlier discussions of the Chinese intellectual property system, see generally Peter K. Yu, *From Pirates to Partners: Protecting Intellectual Property in China in the Twenty-First Century*, 50 AM. U. L. REV. 131 (2000); Peter K. Yu, *From Pirates to Partners (Episode II): Protecting Intellectual Property in Post-WTO China*, 55 AM. U. L. REV. 901 (2006); Peter K. Yu, *Intellectual Property, Economic Development, and the China Puzzle*, in *INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT: STRATEGIES TO OPTIMIZE ECONOMIC DEVELOPMENT IN A TRIPS PLUS ERA* 173 (Daniel J. Gervais ed., 2007); Peter K. Yu, *The Middle Kingdom and the Intellectual Property World*, 13 OR. REV. INT’L L. 209 (2011).

373. FAREED ZAKARIA, *THE POST-AMERICAN WORLD* 38 (2008).



Microbes carry no national passports, neither do they recognize geo-political boundaries or state sovereignty. Propelled by travel, trade, tourism, the phenomenon of globalization, and a host of other factors, public health threats occasioned by an outbreak of a disease in one remote part of the world can easily transcend national boundaries to threaten populations in distant places.<sup>374</sup>

In fact, “[g]lobalization, with its increased trade and travel, meant that outbreaks even in a small prefectural city can quickly become international in scope and threat.”<sup>375</sup> In all three virostories discussed in this Article, the virus began in one place but ended with a large number of victims in another place. SARS was the quickest, the most severe, and the most unexpected. It spread from a village in Foshan, China to a few superspreaders to multiple victims in Canada, Hong Kong, Singapore, Vietnam, and other parts of the world.<sup>376</sup> “By the time [SARS] came under

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374. OBIJIOFOR AGINAM, *GLOBAL HEALTH GOVERNANCE: INTERNATIONAL LAW AND PUBLIC HEALTH IN A DIVIDED WORLD* 6 (2005); accord MARK S. SMOLINSKI ET AL., *MICROBIAL THREATS TO HEALTH: EMERGENCE, DETECTION, AND RESPONSE* xvii (2003) (“Whether naturally occurring or intentionally inflicted, microbial agents can cause illness, disability, and death in individuals while disrupting entire populations, economies, and governments. In the highly interconnected and readily traversed ‘global village’ of our time, one nation’s problem soon becomes every nation’s problem as geographical and political boundaries offer trivial impediments to such threats.”).

375. Alan Schnur, *The Role of the World Health Organization in Combating SARS, Focusing on Efforts in China*, in *SARS IN CHINA*, *supra* note 213, at 31, 50. Similarly, the late John Mann observed:

The world has rapidly become much more vulnerable to the eruption and, most critically, to the widespread and even global spread of both new and old infectious diseases. This new and heightened vulnerability is not mysterious. The dramatic increases in worldwide movement of people, goods, and ideas is the driving force behind the globalization of disease. . . . The lesson is that a health problem in any part of the world can rapidly become a health threat to many or all.

Jonathan M. Mann, *Preface* to LAURIE GARRETT, *THE COMING PLAGUE* xv, xv (1994); see also LEE, *GLOBALIZATION AND HEALTH*, *supra* note 284, at 61–103 (discussing the spatial dimension of global health); McInnes, *supra* note 17, at 46 (“The increased speed of movement of goods and people, and their rapid interaction over wider geographical areas, means that infectious diseases can spread more quickly and over a greater area than ever before . . .”).

376. As an epidemiology professor recounted:

[SARS] remained a fairly local problem until February 21, 2003, the day on which a 65-year-old physician from Guangdong checked into a room on the ninth floor of the Metropole Hotel in Hong Kong, already symptomatic with the infection for which he had been treating people back at home. Although the doctor had little contact with others in the hotel, twelve guests staying on the same floor were eventually diagnosed with SARS. Among them were a Chinese businessman who traveled on to Hanoi to become the index case of the outbreak there, a Singaporean woman who was hospitalized soon after her return to her native city, an elderly woman from Toronto who went home

control in August 2003, 8422 cases had been identified in 29 countries with 908 fatalities.”<sup>377</sup> The disease showed vividly “what could happen in a globally interconnected world where infectious diseases have the capacity to spread rapidly along international air travel routes.”<sup>378</sup>

Finally, if developed countries continue to ignore the needs, interests, conditions, and priorities of the BRICS countries and the African Group, there is a good chance that these countries would be willing to team up with each other to establish a unified position<sup>379</sup>—or worse, a radical unified position. Such development would resonate with the earlier discussion about the increasingly radical turn in intellectual property law and policy.<sup>380</sup> As I noted in the past, if Brazil, China, and India are willing to team up with each other, they could form a formidable alliance rivaling the traditional trilateral alliance among the European Union, Japan, and the United States.<sup>381</sup> This BRICS–African Group alliance likely will have a major impact on the future development of the international intellectual property system.

In sum, it is important to facilitate greater cooperation within both the international intellectual property system and the global health regime. Such cooperation is particularly needed in the area of communicable diseases. As Wolfgang Hein, Sonja Bartsch, and Lars Kohlmorgen observed, “[i]n modern times, the fight against infectious diseases has always depended on international cooperation, requiring nations to coordinate their health and trade strategies with each other.”<sup>382</sup> Likewise, Andrew Price-Smith and Huang Yanzhong also noted:

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to expose her large family in Canada, and a group of others who were admitted to Hong Kong hospitals, where they spread the disease to many of the hospital staff to whom they were exposed.

Megan Murray, *The Epidemiology of SARS*, in *SARS IN CHINA*, *supra* note 213, at 17, 19.

377. McInnes, *supra* note 17, at 44.

378. Christine Loh, *Preface* to *AT THE EPICENTRE*, *supra* note 113, at vii, vii.

379. For discussions of the benefits of setting up an alliance among these countries, see generally Peter K. Yu, *Building IPC4D to Promote Access to Essential Medicines*, in *GLOBAL GOVERNANCE OF HIV/AIDS*, *supra* note 16, at 200; *see also* Peter K. Yu, *Intellectual Property and Asian Values*, 16 MARQ. INTELL. PROP. L. REV. 329, 371 (2012) (arguing that teaming up China, India, and members of the Association of Southeast Asian Nations (ASEAN) in the form of a “Chindiasian” alliance will create a formidable force in future international intellectual property negotiations).

380. *See supra* Part IV.B.1.

381. *See* Yu, *Access to Medicines*, *supra* note 67, at 358–62 (arguing that, if the BRICS countries are willing to join together to form a coalition, it is very likely that the resulting coalition will possess immense power to stop the push by the European Union and the United States to ratchet up global intellectual property standards while threatening to grind the intellectual property harmonization process to a halt).

382. Hein et al., *Conclusion*, *supra* note 347, at 226.

The health of developed countries is increasingly affected by microbes emerging in the poorer reaches of the developing world (e.g., avian influenza, West Nile virus, SARS). Therefore, global public health can be understood as a public good, and the costs of epidemiological surveillance and containment should be borne by the international community, although continued diplomatic leadership by the hegemon (the U.S.) will doubtless be central.<sup>383</sup>

Indeed, poverty and a lack of infrastructure—whether in Asia, Africa, or other parts of the world—could create “weak links” in the global response to pandemics.<sup>384</sup> Because of the climate, crowdedness, and huge population, China and countries in Southeast Asia have also been the breeding places for outbreaks of influenza and other infectious diseases.<sup>385</sup> It is therefore no surprise that the third story about viral sovereignty took place in Indonesia. As Kathryn White and Maria Banda observed in the H1N1 context:

[N]ational pandemic preparedness, by its nature, is an international issue: in a world lacking equitable access to the cure, even the vaccinated would face devastation if the global economy were to stop in its tracks. Instead of hoarding the vaccine, the West ought to release it to the most vulnerable, because the regions the first to be hit would also be the first line of defence.<sup>386</sup>

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383. Price-Smith & Huang, *supra* note 112, at 44.

384. See FIDLER & GOSTIN, *supra* note 179, at 219 (noting the need for development of new governance approaches that “must be global in scope to avoid gaps or ‘weak links’ in the chain of efforts created to prevent, protect against, and respond to pathogenic threats”); see also David Heymann, *Foreword* to FIDLER, *supra* note 27, at xi, xi (“A high proportion of new and emerging infectious diseases come from developing countries, often those least equipped to detect and respond to them early, and to contain them before they spread internationally.”); Adrian Kay & Owain David Williams, *Introduction: The International Political Economy of Global Health Governance*, in GLOBAL HEALTH GOVERNANCE, *supra* note 17, at 1, 10 (“[One] mode of disease transmission is linked to poverty, underdevelopment, the underlying structure and particular spatial characteristics of the global economy, and particularly poor levels of public health infrastructure in many countries.”).

385. See CHAN, *supra* note 360, at 8 (“The three large-scale outbreaks of pandemic viruses in the twentieth century—the 1918 Spanish influenza, the 1956 Asian influenza, and the 1968 Hong Kong influenza—were widely believed to have originated in Asia.”); FIDLER, *supra* note 27, at 72 (“The southeast Asian region had also been the location of two previous scary but ultimately limited viral outbreaks—the H5N1 avian influenza outbreak in Hong Kong in 1997 and the Nipah virus outbreak in 1998–99 in Malaysia. . . . Public health experts have kept an eye on southern China and southeast Asia as a possible, if not the probable, source of the long-anticipated, killer pandemic influenza virus.”); NINA HACHIGIAN & MONA SUTPHEN, *THE NEXT AMERICAN CENTURY: HOW THE U.S. CAN THRIVE AS OTHER POWERS RISE* 41 (2010) (“When it comes to influenza, China is both the problem and the solution. Asia, especially southern China, is ground zero for flu outbreaks.”).

386. White & Banda, *supra* note 190, at 118.

Given the importance of both the BRICS countries and the African Group, policymakers should think more about how to use the current trade and intellectual property provisions to induce more collaboration between the two groups. Article 31*bis*(3) of the TRIPS Agreement, for example, creates a special arrangement that allows less developed countries to aggregate their markets to generate the purchasing power needed to sustain the development of an indigenous region-based pharmaceutical industry.<sup>387</sup> The provision therefore “paves the way for the development of regional supply centers, procurement systems, and patent pools and institutions, while facilitating technical cooperation within the region.”<sup>388</sup> Additional collaboration can also come from the private sector. As UNAIDS documented in its technical brief:

In 2007, Quality Chemicals Limited, in cooperation with Cipla, set up a US\$38 million pharmaceutical plant in Kampala, Uganda to produce antiretrovirals drugs for the domestic market and eventually for export to the East African region and beyond. In February 2009, the plant started producing the triple-therapy combination Triomune (lamivudine, stavudine and nevirapine) and the antimalarial therapy Lumartem (artemisinin and lumefantrine). This plant has been approved for procurement of antiretroviral and malaria medicines drugs by the International Committee of the Red Cross as well as by the WHO Pre-qualification of Medicines program.<sup>389</sup>

From the standpoint of less developed country governments and NGOs, the arrival of these new players could present new opportunities for reshaping the international intellectual property and health systems. Indeed, given the diverse backgrounds, technological capabilities, and innovation paths the BRICS countries and members of the African Group have, the positions they take are likely to be quite different from those of developed countries. As I noted in the inaugural issue of *The WIPO Journal*, “[I]t is premature to assume that less-developed countries, once developed, will always want the existing international intellectual property system. There is a good chance that they may want or need something rather different!”<sup>390</sup> Moreover, as Rorden Wilkinson reminded us:

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387. See TRIPS Agreement art. 31*bis*(3); Yu, *Access to Medicines*, *supra* note 67, at 346 (discussing the strengths and weaknesses of Article 31*bis*(3)).

388. Yu, *Access to Medicines*, *supra* note 67, at 346 (footnotes omitted).

389. UNAIDS Technical Brief, *supra* note 90, at 6.

390. Yu, *Global Intellectual Property Order*, *supra* note 331, at 15. Indeed, because these countries “generate substantial trade surpluses with OECD countries, arguments in favour of price concessions on pharmaceuticals may become less compelling in a wider political arena,”

[T]he evolving character of global governance brings with it moments of opportunity—moments in which pressure can be brought to bear on the emerging patterns of governance. In such moments, alternative possibilities have the potential to emerge, thus altering the way in which global governance is constituted. In this way, identifying the potential for alternative possibilities becomes an intrinsic part of any interrogation of global governance.<sup>391</sup>

#### D. *Negotiated Outcomes*

##### 1. Lesson #6: A Multiplicity of Options

When the three virostories are taken into account, one could not help but notice the significantly different openings, plot twists, and endings in each story. Although all three stories touch on deficiencies and challenges within the international patent system, the approaches taken by the characters in each story and the compromises they struck have been rather different. While compulsory licensing dominated the first story, viral sovereignty claims were asserted in the last story.

Taken together, these three virostories reveal a wide array of approaches that countries can deploy to address the deficiencies in the existing international patent system. To some extent, the stories warn against the rather narrow focus many policymakers have had when considering options to revamp the existing patent system. Although changes in the intellectual property arena are often made based on addition (through new, broader, and stronger rights) and subtraction (through limitations and exceptions),<sup>392</sup> commentators have widely questioned whether the system should be based solely on the property rights model enshrined in the Paris Convention, the TRIPS Agreement, and other international intellectual property treaties.<sup>393</sup>

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even though the poor in these countries continue to suffer from high prices and the resulting inaccessibility of drugs. Abbott, *Cycle of Action*, *supra* note 52, at 29.

391. Rorden Wilkinson, *Global Governance: A Preliminary Interrogation*, in GLOBAL GOVERNANCE, *supra* note 252, at 1, 3.

392. See Daniel J. Gervais, *TRIPS 3.0: Policy Calibration and Innovation Displacement*, in THE DEVELOPMENT AGENDA, *supra* note 305, at 51, 52–54 (advancing the addition and subtraction narratives).

393. See Yu, *Political Economy*, *supra* note 272, at 792 (“As far as policy options are concerned, there is a misguided tendency for policymakers in both developed and less developed countries to assume that the property rights model is the only model, or the best one, that is compliant with the TRIPs Agreement or other commitments under the international intellectual property regime.”).

Proposals abound to suggest the use of other options, including grants, subsidies, prizes, advance market commitments, reputation gains, patent buy-outs, open source drug discovery, patent pools, public-private partnerships, and equity-based systems built upon liability rules.<sup>394</sup>

There have also been growing discussions at both the domestic and international levels about the need for greater limitations and exceptions in the intellectual property system, including the adoption of compulsory licenses, parallel importation, and government use provisions and the introduction of exceptions for early working, research, and development of diagnostics.<sup>395</sup> Beyond patents, commentators have advanced the use of limitations and exceptions in other or broader intellectual property contexts. For example, in a project commissioned by the Open Society Institute, Bernt Hugenholtz and Ruth Okediji discussed the need to develop an international instrument on limitations and exceptions to copyright.<sup>396</sup> A few years earlier, Rochelle Dreyfuss also articulated the need to develop affirmative user rights to facilitate public access to protected materials.<sup>397</sup>

The development of limitations and exceptions is particularly important in the context of global health governance. Such development becomes even more important when communicable diseases are involved. Consider, for example, a special exception for the provision of diagnostic kits for testing patients. Regardless of whether it is HIV, SARS, H5N1, H1N1, MERS, or H7N9, a person infected with the virus may not quickly show distinct symptoms before the virus is spread to other members of the community.<sup>398</sup> Testing and screening therefore will be highly critical to the prevention, control, and treatment of the disease. If a patent holder can prevent others from testing and screening the disease, the results from the public health standpoint could be disastrous, especially when the disease can easily spread from one region to another. The need for testing was,

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394. See generally GENE PATENTS AND COLLABORATIVE LICENSING MODELS, *supra* note 148 (collecting articles discussing patent pools, clearinghouses, open source models, and liability regimes); HO, *supra* note 14, at 355–72 (advancing new approaches to alleviate the impact patents have on short-term access to medicine); INCENTIVES FOR GLOBAL PUBLIC HEALTH, *supra* note 63, at 133–283 (collecting articles discussing prizes, patent pools, and open source drug discovery).

395. See, e.g., 'T HOEN, *supra* note 63, at 39–59; IPR COMMISSION REPORT, *supra* note 29, at 49–51; RODRIGUES, *supra* note 12, at 159–236.

396. See HUGENHOLTZ & OKEDIJI, *supra* note 319.

397. See Rochelle Cooper Dreyfuss, *TRIPS—Round II: Should Users Strike Back?*, 71 U. CHI. L. REV. 21, 21 (2004); see also Yu, *TRIPs and Its Discontents*, *supra* note 274, at 396–401 (outlining the various proposals advanced by scholars).

398. See, e.g., Robert Goldberg, *Disease Control*, WASH. TIMES, May 15, 2003, at A19 (“SARS and HIV are the same in one respect: You can test positive but not show symptoms. That means the only way to control it is through testing, screening and education.”).

indeed, one of the primary reasons why the patents surrounding BRCA1 and BRCA2—genes associated with a predisposition to breast and ovarian cancers—were challenged in *Association for Molecular Pathology v. Myriad Genetics, Inc.*<sup>399</sup>

While the three virostories show that a wide and diverse array of policy options exists, they also indicate that these options can be developed in many different ways. In fact, the debate concerning access to essential medicines in less developed countries does not always end with these countries on the defensive end, demanding special and differential treatment. With collective insights and the assistance of outside experts, such as academics and NGOs from the developed world,<sup>400</sup> these countries have now been slowly moving toward the offensive end, demanding compromises from both within the system and without. In the future, the development of the international patent system is likely to be highly intriguing as the larger developing countries, such as Brazil, China, and India, become more economically powerful, more technologically proficient, and more assertive on the negotiating front.<sup>401</sup>

Moreover, as the three virostories have shown, the discontent with the existing international patent system is not limited to only less developed countries. In fact, a heterogeneous group of countries has been dissatisfied with the system. Because of their different economic strengths and technological capacities, the policy choices and responses they made are also quite varied. For example, the more technologically proficient countries<sup>402</sup> have chosen to compete with developed countries—either under

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399. 133 S. Ct. 2107, 2107 (2013). “Genetic tests are an important component of health care services, as they provide a way to establish difficult diagnoses and to detect persons at risk, before expressing the disease. Testing is also useful in planning clinical interventions that may benefit the concerned individuals, by attenuating or even efficiently treating their disease.” Van Overwalle, *supra* note 149, at 387–88.

400. See Yu, *Access to Medicines*, *supra* note 67, at 377 (noting the important role NGOs, academics, and media from developed countries can play in promoting access to essential medicines in the less developed world).

401. On the emergence of these countries, in particular China, as innovative powers, see generally Peter K. Yu, *Five Oft-repeated Questions About China's Recent Rise as a Patent Power*, 2013 CARDOZO L. REV. DE NOVO 78; Peter K. Yu, *Intellectual Property and Asian Values*, 16 MARQ. INTELL. PROP. L. REV. 329 (2012); Peter K. Yu, *The Middle Intellectual Property Powers*, in LAW AND DEVELOPMENT IN MIDDLE-INCOME COUNTRIES: AVOIDING THE MIDDLE-INCOME TRAP 84 (Randall Peerenboom & Tom Ginsburg eds., 2014); Peter K. Yu, *The Rise and Decline of the Intellectual Property Powers*, 34 CAMPBELL L. REV. 525 (2012).

402. See Shammad Basheer & Annalisa Primi, *The WIPO Development Agenda: Factoring in the “Technologically Proficient” Developing Countries*, in IMPLEMENTING THE WORLD INTELLECTUAL PROPERTY ORGANIZATION'S DEVELOPMENT AGENDA 100 (Jeremy de Beer ed., 2009) (differentiating countries based on technological proficiency, rather than economic development).

the same rules (as in the case of Versitech in Hong Kong in the second story) or through the adjustment or reinterpretation of these rules (as in the case of the Indian generic pharmaceutical industry in the first story). By contrast, the less technologically proficient countries have no choice but to rely on special and differential treatment. Nevertheless, they now add to this special treatment their demands for greater protection of genetic resources (as in the case of the Indonesian government in the third story). Thus, the positions they take have not always been TRIPS-minus; where beneficial, they have also called for the creation of new TRIPS-plus rights.

Indeed, the need to protect genetic resources is one of the primary reasons why less developed countries were very eager to link the TRIPS Agreement to the CBD. Paragraph 19 of the Doha Ministerial Declaration explicitly “instruct[ed] the [TRIPS] Council . . . to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1.”<sup>403</sup> Taking advantage of this linkage, a group of less developed countries advanced the proposal for Article 29*bis* of the TRIPS Agreement, as discussed earlier.<sup>404</sup>

## 2. Lesson #7: Rights and Responsibilities

Although Article 7 of the TRIPS Agreement, which outlines the Agreement’s objectives, states that “[t]he protection and enforcement of intellectual property rights should contribute . . . to a balance of rights and obligations,” the Agreement emphasizes rights more than responsibilities.<sup>405</sup> As the High Commissioner for Human Rights declared in her report:

[W]hile the Agreement identifies the need to balance rights with obligations, it gives no guidance on how to achieve this balance. On the one hand, the Agreement sets out in considerable detail the content of intellectual property *rights*—the requirements for the grant of rights, the duration of protection, the modes of enforcement. On the other hand, the Agreement only alludes to the *responsibilities* of [intellectual property] holders that should

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403. WTO, Ministerial Declaration of 14 November 2001, ¶ 19, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002).

404. See *supra* text accompanying notes 368–69.

405. *High Commissioner’s Report*, *supra* note 46, ¶ 23; see also Yu, *Objectives and Principles*, *supra* note 134, at 1035–37 (discussing the need to identify intellectual property rights holders’ obligations and to build obligations, responsibilities, maximum standards, and affirmative rights into the intellectual property system).



balance those rights in accordance with its own objectives. The prevention of anti-competitive practices and the abuse of rights, the promotion of technology transfer, special and differential treatment for least developed countries are merely referred to—but unlike the rights it sets out, the Agreement does not establish the content of these responsibilities, or how they should be implemented.<sup>406</sup>

While the TRIPS Agreement mentions the word “right” more than a hundred times, it mentions “responsibilities” only once.<sup>407</sup> Even in that occurrence, the word refers to the responsibilities of the TRIPS Council, not the responsibilities of intellectual property rights holders.

The approach taken in the intellectual property arena stands in sharp contrast to the approach taken in the human rights arena. For example, in its authoritative interpretation of the International Covenant on Economic, Social and Cultural Rights,<sup>408</sup> the Committee on Economic, Social and Cultural Rights states clearly that “intellectual property is a social product . . . [with] a social function” and that “the private interests of authors should not be unduly favoured and the public interest in enjoying broad access to their productions should be given due consideration.”<sup>409</sup> In an earlier interpretative comment on the right to health, the Committee also declares: “While only States are parties to the Covenant and thus ultimately accountable for compliance with it, all members of society— . . . including . . . the private business sector—have responsibilities regarding the realization of the right to health.”<sup>410</sup>

Like these general interpretive comments, the preamble to the Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines states: “Pharmaceutical companies, including innovator, generic and biotechnology companies, have human rights responsibilities in relation to access to medicines.”<sup>411</sup> Guideline 26, in particular, stipulates that these companies “should make and respect a public commitment not to lobby for more demanding protection of intellectual property interests than those

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406. *High Commissioner's Report*, *supra* note 46, ¶ 23.

407. TRIPS Agreement art. 68.

408. International Covenant on Economic, Social and Cultural Rights, Dec. 16, 1966, 993 U.N.T.S. 3.

409. *General Comment No. 17*, *supra* note 270, ¶ 35.

410. *General Comment No. 14*, *supra* note 139, ¶ 42.

411. Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical & Mental Health, *Rep. of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, at 15, transmitted by Note of the Secretary General, U.N. Doc. A/63/263 (Aug. 11, 2008) (by Paul Hunt), available at [http://www.who.int/medicines/areas/human\\_rights/A63\\_263.pdf](http://www.who.int/medicines/areas/human_rights/A63_263.pdf).

required by TRIPS, such as additional limitations on compulsory licensing.”<sup>412</sup>

In recent years, commentators have widely discussed the need to build obligations, responsibilities, maximum standards, and affirmative rights into the intellectual property system. As Jacqueline Lipton pointed out, when laws borrowed from traditional property theory are applied in the information property context, there is a tendency to overlook the fact that “traditional Property rights entail significant concurrent obligations or responsibilities imposed on the proprietary owner as an incident of their Property ownership.”<sup>413</sup> Jerome Reichman, Henning Grosse Ruse-Khan, and I have also independently articulated the important roles Articles 7 and 8 of the TRIPS Agreement can play in the international intellectual property regime.<sup>414</sup> To a large extent, the lack of focus on responsibilities in the TRIPS Agreement has tilted the balance so far toward rights holders that the Agreement no longer fulfills the Article 7 objective of achieving “a balance of rights and obligations.”<sup>415</sup>

Even worse, developed countries increasingly push less developed countries to introduce heightened obligations to enforce intellectual property rights, even though the preamble to the TRIPS Agreement explicitly states that “intellectual property rights are private rights.”<sup>416</sup> Cases in point are those provisions in ACTA, the TPP, and other nonmultilateral trade agreements that call for greater criminal enforcement, *ex officio* authority, and data exclusivity on the part of regulatory authorities. These demands gradually shift the costs and responsibilities from private rights holders to national governments.<sup>417</sup>

412. *Id.* at 21.

413. Jacqueline Lipton, *Information Property: Rights and Responsibilities*, 56 FLA. L. REV. 135, 148 (2004).

414. See Henning Grosse Ruse-Khan, *Proportionality and Balancing Within the Objectives for Intellectual Property Protection*, in INTELLECTUAL PROPERTY AND HUMAN RIGHTS 161, 169–91 (Paul L.C. Torremans ed., 2008); J.H. Reichman, *The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?*, 32 CASE W. RES. J. INT’L L. 441, 461 (2000); Yu, *Objectives and Principles*, *supra* note 134, at 1018–46.

415. TRIPS Agreement art. 7.

416. *Id.* pmbl., recital 4; see also Peter K. Yu, *TRIPS Enforcement and Developing Countries*, 26 AM. U. INT’L L. REV. 727, 747–54 (2011) (discussing the private nature of intellectual property rights); UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT: AN AUTHORITATIVE AND PRACTICAL GUIDE TO THE TRIPS AGREEMENT 11 & n.21 (2005) [hereinafter TRIPS RESOURCE BOOK] (stating that a senior member of the WTO Secretariat recalling that “the reference to ‘private rights’ was included at the insistence of the Hong Kong delegation, which wanted clarification that the enforcement of IPRs is the responsibility of private rights holders, and not of governments”).

417. See Li, *supra* note 51, at 28 (“Responsibility of enforcement has cost implications. . . . [B]y shifting responsibility, it would shift the cost of enforcement from private parties to the

From the standpoint of global health governance, such a shift is highly undesirable, as stronger enforcement often comes with a hefty price tag and difficult trade-offs.<sup>418</sup> Given the limited resources in many less developed countries, an increased use of resources in the enforcement area will inevitably lead to the withdrawal of resources from other competing, and at times more important, public needs. An example of these competing needs that easily comes to mind is the protection of public health.<sup>419</sup> As the IPR Commission noted in its influential final report:

[A]s state enforcement of IPRs is a resource-intensive activity, there is a strong case for developing countries to adopt IPR legislation that emphasises enforcement through a civil rather than a criminal justice system . . . [W]e note that developing countries have come under pressure from industry which advocates enforcement regimes based on state initiatives for the prosecution of infringements. Such pressures should be resisted, and right owners assume the initiative and costs of enforcing their private rights.<sup>420</sup>

In sum, policymakers should take account of both rights and responsibilities when developing laws and policies. In doing so, they will be in a better position to strive for balance between the protection and enforcement of intellectual property rights on the one hand and the fulfillment of international health and human rights obligations on the other. As commentators rightly reminded us, the protection of intellectual property rights should not be seen as an end in itself, but rather a means to an end.<sup>421</sup>

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government and ensure right-holders are beneficiaries without taking responsibility.”); Henning Grosse Ruse-Khan, *Re-delineation of the Role of Stakeholders: IP Enforcement Beyond Exclusive Rights*, in *INTELLECTUAL PROPERTY ENFORCEMENT*, *supra* note 51, at 43, 51–52 (noting the trend of “externalizing the risks and resources to enforce [intellectual property] rights away from the originally responsible rights-holders towards state authorities”).

418. See generally Yu, *Enforcement, Economics and Estimates*, *supra* note 51.

419. Other needs include purification of water, generation of power, reduction of child mortality, provision of education, promotion of public security, building of basic infrastructure, reduction of violent crimes, relief of poverty, elimination of hunger, promotion of gender equality, protection of the environment, and responses to terrorism, illegal arms sales, human and drug trafficking, illegal immigration, and corruption. See Yu, *TRIPS Enforcement and Developing Countries*, *supra* note 416, at 751 & n.125.

420. IPR COMMISSION REPORT, *supra* note 29, at 147.

421. See *id.* at 6 (stating that intellectual property rights should be regarded “as instruments of public policy which confer economic *privileges* on individuals or institutions solely for the purposes of contributing to the greater public good” and that the conferred privileges should be “a means to an end, not an end in itself”); TRIPS RESOURCE BOOK, *supra* note 416, at 125–26 (“Article 7 makes it clear that IPRs are not an end in themselves.”); Marco Ricolfi, *Is There an Antitrust Antidote Against IP Overprotection Within TRIPs?*, 10 MARQ. INTELL. PROP. L. REV. 305, 326 (2006) (“A closer reading of TRIPs . . . shows that [intellectual property] protection

In the global health context, such protection should be harnessed to promote the protection of public health and greater access to essential medicines in both developed and less developed countries. The introduction of responsibilities into the international intellectual property system would also resonate with the ongoing discussions of responsibilities in national healthcare debates. As Adrian Kay and Owain David Williams observed:

[N]eoliberal healthcare states use the technique of responsibilisation; citizens become “responsibilised” by making them see health risks and outcomes such as illness or disease as their own individual responsibility, with the corollary that the policy problem of health governance is framed as one of encouraging “self-care”. . . . We [also] witness responsibilisation in many of the current debates in advanced capitalism over tobacco, obesity, and access to medicines; they reveal the dominant neoliberal thrust in health, it is our responsibility to remain free of illness so as to be able to work and to care for our dependents such as children and elderly parents.<sup>422</sup>

#### CONCLUSION

The movie *Contagion* paints a grim picture where a mysterious disease quickly travels from Macau, China to other parts of the world. In the first few scenes of the movie, people die and suffer without knowing where the disease came from, what the disease entails, and how doctors could prevent or treat the disease. The quick and wide spread of this contagion eventually leads to quarantines, deaths, emotional distress, crimes, and ultimately mass panic. The movie also raises important questions about the readiness of our public health system and our ability to trust governments to do the right thing.

Although this movie features heavily dramatized events, its important point that a failure to prevent and control a highly contagious disease can take a heavy toll on society is not lost on the audience. The inclusion of scenes from different parts of the world also drives home the point that viruses can spread quickly from one country to another and often by accident—something that has already been vividly demonstrated by the spread of HIV/AIDS, SARS, and H1N1.

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and enforcement are seen as means rather than ends in themselves both because the larger ends encompass freedom of trade . . . and because the international community is committed to taking into account other non-trade and non-[intellectual property] factors while shaping [intellectual property] protection.”).

422. Kay & Williams, *supra* note 384, at 6–7 (citations omitted).

The three virostories discussed in this Article have shown that the intellectual property system can play a very important role in addressing the concerns caused by communicable diseases and the spread of viruses. Whether that role is constructive or destructive will depend largely on whether the system is tailored to the needs, interests, conditions, and priorities of each individual member of the international community. While we need the development of new pharmaceuticals to prevent, control, treat, or cure these diseases, we also need to ensure that the needed medicines are available and affordable in all corners of the world.

The discussion of issues at the intersection of intellectual property and public health becomes even more important considering that diseases can easily spread from rich developed countries to poor less developed countries, or vice versa. Sub-Saharan Africa needs medicines to deal with HIV/AIDS, malaria, and tuberculosis just as the United States had urgency for ciprofloxacin in response to the anthrax scare shortly after the September 11 terrorist attacks.<sup>423</sup> The three virostories discussed in this Article undoubtedly provide important reminders about the need for greater global collaboration to harness the international patent system to provide mutual benefits.

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423. See Yu, *The International Enclosure Movement*, *supra* note 14, at 874 (noting the United States' need for ciprofloxacin following the anthrax attacks in Boca Raton, New York, and Washington in 2001).